PATENT ABSTRACTS OF JAPAN

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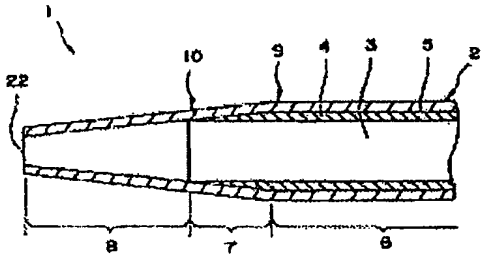
(54) BLOOD VESSEL CATHETER

(57)Abstract:
PURPOSE: To achieve higher safety with the prevention of damage to an internal wall of a blood vessel by a method wherein a main part of a catheter main body having an inner tube with high rigidity and an outer tube with rigidity lower than the inner tube and moreover, the outer tube sticks out by a specified length from the tip of the inner tube.
CONSTITUTION: A catheter body 2 has a main part which is arranged to be a double structure which comprises an inner tube 4 and an outer tube 5 joined closely on the external surface thereof 4 and the inner tube 4 is made of a material with higher rigidity while the outer tube 5, a soft material. The catheter body 2 is made up of a base part 6 of a double structure, an intermediate part 7 and a tip part 8 having the outer tube 5 alone in the order from the mounting end side. At the base part 6, the outer diameter of the catheter body 2 is almost constant in the longitudinal direction of the tip 22. At the intermediate part 7, the outer diameter of the catheter body 2 decreases gradually toward the tip 22 while the inner tube 4 also has the outer diameter thereof decreasing gradually toward the tip 22. Thus, the thickness of the inner tube 4 becomes thin gradually and the rigidity thereof decreases continuously. At the tip part 8, the inner tube 4 lacks. With the outer tube 5 alone, the outer diameter of the catheter body 2 decreases gradually in the direction of the tip.



* NOTICES *

1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

CLAIMS

[Claim(s)]
[Claim 1]It has the catheter body in which made double tube structure which consists of an inner tube and an outer tube stuck to an outside surface of this inner tube, it applied at a tip from a end face, and a lumen was formed in an inside, A base which a rate of bending flexibility of said inner tube is a larger vessel catheter than a rate of bending flexibility of said outer tube, and said catheter body has an almost constant outer diameter to a longitudinal direction, and consists of said inner tube and said outer tube.
Pars intermedia which consists of said inner tube which it is extended toward the direction of a tip of a catheter body from a tip of this base, and the outer diameter dwindles toward the direction of a tip at least, and said outer tube.
Said outer tube which it is extended toward the direction of a tip of a catheter body from a tip of this pars intermedia, and the outer diameter dwindles toward the direction of a tip.
It is the vessel catheter provided with the above, and the smooth surface where an outside surface of a catheter body continued, respectively is formed.

[Claim 2]The vessel catheter according to claim 1 which an outer diameter of said inner tube in said pars intermedia dwindles toward the direction of a tip.
[Claim 3]The vessel catheter according to claim 1 or 2 which thickness of said outer tube in said tip part dwindles toward the direction of a tip.
[Claim 4]The vessel catheter according to any one of claims 1 to 3 whose rates of bending flexibility of said inner tube (ASTM D-790, 23 **) are 1500-15000 kg / cm^2.
[Claim 5]The vessel catheter according to any one of claims 1 to 4 with which said inner tube comprises a polyamide elastomer.
[Claim 6]The vessel catheter according to any one of claims 1 to 5 whose rates of bending flexibility of said outer tube in said tip part (ASTM D-790, 23 **) are 5-1500 kg / cm^2.
[Claim 7]The vessel catheter according to any one of claims 1 to 6 with which said outer tube comprises a polyester elastomer.
[Claim 8]The vessel catheter according to any one of claims 1 to 7 with which an outside surface of said catheter body is covered with hydrophilic polymer material.

[Translation done.]

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Industrial Application]This invention relates to the vessel catheter used for superselective pouring of drugs, such as an intravascular operation and an anticancer drug, angiography, etc.
[0002]
[Description of the Prior Art]In recent years, a surgical operation is not conducted but the intravascular operation which treats the lesions (an aneurysm, an arteriovenous malformation tumor, etc.) which inserted the catheter into the blood vessel endermically and were rich in vascular lesion and a blood vessel prospers. In such technique, crookedness meandering must be carried out intricately and a vessel catheter must be selectively inserted in the specific part of a thin blood circulatory system with much branching.
[0003]For example, in the intravascular operation called the plug way given to an aneurysm, an arteriovenous malformation tumor, etc. which are looked at by the cerebral blood vessel etc. The tip of a thin vessel catheter is selectively inserted to the affected part within a brain, or its neighborhood, A coil is poured into granular plug substances, such as liquefied plug substances, such as a dimethylsulfoxide solution of cyanoacrylate and an ethylene-vinylalcohol copolymer, and granulation of polyvinyl alcohol, and it from the tip of a vessel catheter. Thus, the vessel catheter of a narrow diameter according to it is used for administration of the drugs to a thin blood vessel, or pouring of a contrast medium.
[0004]Therefore, to the vessel catheter of such a narrow diameter. To chemical and biosafety [which are required of the usual vessel catheter], in addition, in order to require the operativity which can be inserted in the blood circulatory system of a thin complicated pattern with quick and positive selectivity and to pour in further the plug substance mentioned above, Chemical resistance, the solvent resistance which does not produce deterioration when especially solvents, such as dimethyl sulfoxide, are contacted, etc. are required.
[0005]What is called pushing nature which the power which a way person pushes in may be certainly delivered to the tip side from the end face side of a catheter in order to make the inside of a blood vessel insert in when the above-mentioned operativity of a vessel catheter is explained in full detail, The torque convectivity which the torque applied in the end face side of a catheter may be certainly delivered to the tip side, with the conformity (the following and "the conformity over a guide wire" -- or it is only called "flattery nature") which can progress without damaging a blood vessel wall smoothly along with the guide wire in which the inside of the crooked blood vessel was inserted beforehand. Also after a catheter tip's reaching to the target place and drawing out a guide wire, the kink-proof nature which bending does not produce is needed for a catheter by the curve of a blood vessel, and the crooked part. The lubricity (slidability by reduction of a coefficient of friction) of the outside surface of a catheter is needed as one of the greatest factors that give these character to a catheter.
[0006]Among these, as conventional technology for giving pushing nature and the conformity over a guide wire, The vessel catheter which comprised a comparatively softness outer tube which has the portion which covered the outside surface of a comparatively hard inner tube and this inner tube, and was projected from the tip of the inner tube and whose main long part is double tube structure is developed and used. In such a vessel catheter, the thing of the following combination is proposed as that of the component of an inner tube and an outer tube.
[0007]In the real table No. 500013 [Showa 60 to], and the correspondence U.S. Pat. No. 4385635 item, polyamide is used for an inner tube, and urethane is used for an outer tube, and the vessel catheter formed in tapered shape so that the inside diameter might increase the tip end part of an inner tube gradually is indicated. However, in this vessel catheter, since an outer tube is a product made from urethane, it is lacking in said solvent resistance, and is not suitable for the catheter used for a plug way.
[0008]In this device, since rigidity changes from a part for the double tube part of polyamide and urethane rapidly in the boundary part which shifts to a part for 1-fold tube part of urethane, a catheter body also has the fault of being easy to produce bending (kink). In particular, in a part for 1-fold tube part of urethane, an outer

diameter and an inside diameter are constant, since rigidity is not gradually decreasing toward a tip, it is the cause by which stress concentration arises from a double tube in the boundary part which shifts to one detonator, and this produces a kink, and flattery nature is also inferior. repeating intravascular operation especially -- a line -- to inside, due to construction material fatigue, in being excessive, a report that the boundary part which shifts to one detonator cut from the double tube appears here and there.
[0009]In JP,62-17082,Y, silicone rubber is used for an outer tube and the vessel catheter using the hard resin chosen as the inner tube from polyethylene, polypropylene, a fluoro-resin, and hard vinylchloride resin is indicated. In [although there is solvent resistance in this vessel catheter (except for hard vinylchloride resin)] the boundary part of the portion (body part 4) of a double tube, and the portion (tip part 3) of one detonator, Since the level difference equivalent to the thickness of an inner tube is formed in the tube lumen, it is easy to produce bending in this portion, and said kink-proof nature is inferior. Kink-proof nature is inferior similarly about combination in recent years in the inner tube made from polypropylene put in practical use, and the outer tube made from an ethylene-vinylacetate copolymer.
[0010]In JP,59-156353,A, the tubular body by the side of the base made of nylon and the tip part made from a polyether polyamide copolymer are united, and the vessel catheter which marked the pliability of the tip part moderately is indicated. However, this vessel catheter is not what makes double pipe construction, Since it is what unites and connects a dissimilar material, there are fear of cutting in a fusion part and a possibility of a level difference being formed in an outside surface and doing damage to a blood vessel wall at the time of catheter implantation, and there is a fault that the still more nearly special manufacturing installation for fusion of polymer must be used.
[0011]In the U.S. Pat. No. 4636346 item, the guiding catheter which has the principal part of 3-fold tube structure and a tip part of the double tube structure (the interlayer of the principal part is lacked) extended in the direction of a tip from it is indicated. Since this catheter is a catheter for the guide for inserting other catheters in that lumen (lumen), and deriving to a target part, let it be a premise to take the inside diameter of a lumen as greatly as possible.
Therefore, it is difficult to apply to the vessel catheter of the narrow diameter mentioned above as a matter of fact.

[0012]Since each vessel catheter which was mentioned above was lacking in the lubricity of the outside surface and inferior to the slidability within a blood vessel, it was difficult for it to make a vessel catheter arrive at a target part safely for a short time.
[0013]
[Problem(s) to be Solved by the Invention]The purpose of this invention is excellent in operativity, such as pushing nature, conformity, kink-proof nature, and there is little vascular injury, it is excellent in safety, and there is in providing a vessel catheter suitable also for the technique especially to the blood vessel of a narrow diameter.
[0014]
[Means for Solving the Problem]Such a purpose is attained by this invention of following the (1) - (8).
[0015](1) Double tube structure which consists of an inner tube and an outer tube stuck to an outside surface of this inner tube is made, Have the catheter body in which it applied at a tip from a end face, and a lumen was formed in an inside, and from a rate of bending flexibility of said outer tube, a rate of bending flexibility of said inner tube is a large vessel catheter, and said catheter body, A base where an outer diameter is almost constant to a longitudinal direction, and becomes it from said inner tube and said outer tube, Pars intermedia which consists of said inner tube which it is extended toward the direction of a tip of a catheter body from a tip of this base, and the outer diameter dwindles toward the direction of a tip at least, and said outer tube, It is extended toward the direction of a tip of a catheter body from a tip of this pars intermedia, and comprises a tip part which consists of said outer tube which the outer diameter dwindles toward the direction of a tip, Near the boundary part of said base and said pars intermedia, and in [apply to said tip part from said pars intermedia, and the flexural rigidity of a catheter body gradually decreases, and] near the boundary part of said pars intermedia and said tip part, A vessel catheter currently forming the smooth surface where an outside surface of a catheter body continued, respectively.
[0016](2) A vessel catheter given in the above (1) which an outer diameter of said inner tube in said pars intermedia dwindles toward the direction of a tip.
[0017](3) A vessel catheter the above (1) which thickness of said outer tube in said tip part dwindles toward the direction of a tip, or given in (2).
[0018](4) A vessel catheter the above (1) whose rates of bending flexibility of said inner tube (ASTM D-790, 23

**) are 1500-15000 kg / cm^2 thru/or given in either of (3).
[0019](5) A vessel catheter the above (1) by which said inner tube is constituted from a polyamide elastomer thru/or given in either of (4).
[0020](6) A vessel catheter the above (1) whose rates of bending flexibility of said outer tube in said tip part (ASTM D-790, 23 **) are 5-1500 kg / cm^2 thru/or given in either of (5).
[0021](7) A vessel catheter the above (1) by which said outer tube is constituted from a polyester elastomer thru/or given in either of (6).
[0022](8) A vessel catheter the above (1) with which an outside surface of said catheter body is covered with hydrophilic polymer material thru/or given in either of (7).
[0023]
[Function]The vessel catheter of this invention A rigid inner tube with a high main part of a catheter body, Since it comprises a double tube which combined the rigid low outer tube compared with this, an outer tube carries out predetermined length projection from the tip of an inner tube further and the flexible catheter tip part is formed, Not to mention the usual artery and vein whose path is comparatively large, pushing nature, conformity, and kink-proof nature outstanding in a detailed and complicated blood vessel like a cerebral blood vessel or other peripheral vessels, for example are demonstrated, it has positive selectivity in vascular bifurcation, and safety is also still higher.
[0024]When it furthermore explains in full detail, in the vessel catheter of this invention the portion of double tube structure, It comprises a base where the outer diameter of a catheter body is almost constant to a longitudinal direction, and pars intermedia which the outer diameter of a catheter body dwindles toward the direction of a tip, Comprise only an outer tube more flexible than pars intermedia to the tip side, and since the tip part which an outer diameter dwindles toward the direction of a tip is formed, it applies to pars intermedia from a base, The outstanding pushing nature and torque convectivity are demonstrated, it applies to a tip part from pars intermedia, the outstanding conformity over the guide wire inserted in the blood vessel crooked since the rigidity of the catheter body decreased continuously over the whole region mostly is demonstrated, and also bending (kink) is prevented.
[0025]In this case, in pars intermedia and a tip part, since the outer diameter is gradually decreasing toward the direction of a tip, the insertion nature at the time of pushing in a catheter in a blood vessel (performance traverse) and the selectivity in vascular bifurcation are high. In the boundary part of a base and pars intermedia, and the boundary part of pars intermedia and a tip part, since the outside surface of a catheter body forms the continuous smooth surface without a level difference, respectively, there are few stimuli to a blood vessel and they do not do damage.
[0026]So that the outer diameter of the inner tube in pars intermedia may gradually decrease toward the direction of a tip, That is, the rigid abrupt change and stress concentration in said boundary part are lost, and it becomes difficult to produce a kink by forming the outside surface of an inner tube in tapered shape by adjusting appropriately the elastic modulus of an inner tube and an outer tube with selection of material or a size again. Since rigidity is comparatively high near a room temperature, and especially the inner tube that comprised a polyamide elastomer or a polyester elastomer is excellent in pushing nature and becomes flexible near body temperature, it adapts itself to crookedness of a blood vessel well, and flattery nature and kink-proof nature increase further.
[0027]Safety increases much more, without contacting blood etc., carrying out formation in the lubricous surface, and the operativity within a blood vessel improving further, and damaging a blood vessel wall, when the outside surface of a catheter body is covered with hydrophilic polymer material.
[0028]
[Elements of the Invention]Hereafter, this invention is explained in detail based on a good example shown in an accompanying drawing. A top view in which drawing 1 shows an example of an entire configuration of a vessel catheter of this invention, and drawing 2 are drawings of longitudinal section expanding and showing composition near the tip part of a vessel catheter shown in drawing 1. By drawing 2, in order to understand easily, especially a diameter direction of a vessel catheter is expanded and it is shown typically.
[0029]As shown in drawing 1, the vessel catheter 1 of this invention comprises the catheter body 2 and the hub 11 with which the end face 21 of this catheter body 2 was equipped. The lumen 3 is formed in an inside, covering the catheter body 2 at the tip 22 from the end face 21. This lumen 3 serves as channels, such as a drug solution.
At the time of insertion in a blood vessel of the vessel catheter 1, a guide wire is inserted in in the lumen 3. The hub 11 functions also as a grasping part at the time of functioning as inlets, such as a drug solution into the lumen 3, and a loading slot of said guide wire, and operating the vessel catheter 1.

[0030]As shown in drawing 2, double tube structure which consists of the outer tube 5 which the catheter body 2 was stuck to the main part on an outside surface of the inner tube 4 and this inner tube 4, and was joined is made. The inner tube 4 comprises a rigid large material comparatively.
The outer tube 5 comprises a comparatively flexible material.
The catheter body 2 comprises the base 6, the pars intermedia 7, and the tip part 8 sequentially from the end face 21 side. Among these, the base 6 and the pars intermedia 7 are making said double tube structure, and the tip part 8 comprises only the outer tube 5.
[0031]In the base 6, an outer diameter of the catheter body 2 is almost constant to a catheter longitudinal direction. It is preferred that an inside diameter (diameter of the lumen 3) of the catheter body 2 is almost constant similarly.
[0032]In the pars intermedia 7, an outer diameter of the catheter body 2 is gradually decreasing toward the direction of the tip 22 (henceforth the direction of a tip). In the pars intermedia 7, it is preferred that an outer diameter of the inner tube 4 gradually decreases toward the direction of a tip, and, as for an inside diameter of the catheter body 2, it is still more preferred that it is almost fixed to a longitudinal direction. Thereby, thickness of the inner tube 4 becomes thin gradually toward the direction of a tip, and the rigidity also decreases continuously.
[0033]The inner tube 4 lacks and the tip part 8 comprises only the outer tube 5. In this tip part 8, an outer diameter of the catheter body 2 is gradually decreasing toward the direction of a tip. thickness of the outer tube 5 like a graphic display, in the tip part 8, in order to make regularity or its percentage reduction low for a diameter of the lumen 3 and to improve the insertion nature of a guide wire although it may be about 1 law at a catheter longitudinal direction, It is preferred that the outer-tube 5 whole region or a part of thickness gradually decrease toward the direction of a tip. It is advantageous also to decreasing the rigidity of the tip part 8 continuously in the direction of a tip to have such composition, and it is preferred also for improvement in conformity and safety.
[0034]As it is indicated in drawing 2 as a cone angle of an outside surface of the catheter body 2 in the pars intermedia 7, and a cone angle of an outside surface of the catheter body 2 in the tip part 8, it may be the same or may differ. In the boundary part 9 of the base 6 and the pars intermedia 7, the smooth surface (for example, field which curves to a catheter longitudinal direction) where an outside surface of the catheter body 2 continued is formed, and a level difference is not formed substantially. The boundary part 9 is prevented also from that there are few stimuli to a blood vessel and they also do damage to a blood vessel wall on the occasion of catheter implantation by this, and being prevented, being caught when passing through a loading slot of a catheter implantation instrument like a sheath moreover, and wearing out.
[0035]Also in the boundary part 10 of the pars intermedia 7 and the tip part 8, since an outside surface of the catheter body 2 forms a successive surface and a level difference is not formed similarly, the same effect as the above is acquired. When a cone angle of an outside surface of the catheter body 2 in the pars intermedia 7 differs from a cone angle of an outside surface of the catheter body 2 in the tip part 8, It is preferred that an outside surface of the catheter body 2 in the boundary part 10 forms the continuous smooth surface like said boundary part 9.
[0036]As a component of the inner tube 4, for example Polyolefines, such as polypropylene and polyethylene, Polyester, such as polyamide, polyethylene terephthalate, and polybutylene terephthalate, Fluororesin, such as polyurethane, polyvinyl chloride, polystyrene system resin, and an ethylene-tetrafluoroethylene copolymer, Although it is usable in resin which has various flexibility, such as polyimide, and various elastomers, such as a polyamide elastomer, a polyester elastomer, and a polyurethane elastomer, Also especially in it, a polyamide elastomer or a polyester elastomer is preferred, and a polyamide elastomer is more preferred. By using such a material, rate of bending flexibility optimal as the inner tube 4 is obtained, and solvent resistance is high, and it excels in kink-proof nature etc. Since rigidity is comparatively high near a room temperature, and a polyamide elastomer and a polyester elastomer are excellent in pushing nature or torque convectivity and become flexible near body temperature, after inserting in the inside of the body, it gets used better in crookedness of a blood vessel, and flattery nature and kink-proof nature increase further.
[0037]With a polyamide elastomer, here, for example Nylon 6, the nylon 64, Nylon 66, Nylon 610, Nylon 612, Nylon 46, the nylon 9, NANAIRON 11, Nylon 12, N-alkoxy methyl denaturation nylon, Various aliphatic series or aromatic polyamide like hexamethylenediamine isophthalic acid polycondensation polymer and METAKISHI roil diamine adipic acid polycondensation polymer is used as a hard segment, A block copolymer which uses polymer, such as polyester and polyether, as a soft segment is typical, In addition, they are polymer alloys (a polymer blend, graft polymerization, random polymerization, etc.) of said polyamide and resin which is rich in pliability, a thing which elasticity-ized said polyamide with a plasticizer etc., and a concept also containing these mixtures further.

[0038]As for said plasticizer, it is preferred to use what is hard to be extracted in a solvent, blood, etc. With a polyester elastomer, saturated polyester, such as polyethylene terephthalate and polybutylene terephthalate, A block copolymer with polyether or polyester is typical, in addition are what elasticity-ized these polymer alloys and said saturated polyester with a plasticizer etc., and a concept also containing these mixtures further.
[0039]Various additives, such as an alloy-ized agent, a compatibilizer, a hardening agent, a softener, a contrast medium, stabilizer, and colorant, may be blended with said polyamide elastomer or a polyester elastomer if needed. In this case, it is preferred that an addition ingredient uses what is hard to be extracted in a solvent, a drug solution, blood, etc. Although construction material of the inner tube 4 is usually made the same along with the longitudinal direction, the presentation may change with parts if needed.
[0040]As a component of the outer tube 5, they are polypropylene and polyethylene (especially), for example. Polyolefines, such as low density polyethylene and an ethylene-vinylacetate copolymer, Although it is usable in resin and an elastomer which are rich in the various pliability of said polyamide elastomer, said polyester elastomer, a polyurethane elastomer, soft polyvinyl chloride, a polystyrene elastomer, a fluorinated elastomer, silicone rubber, latex rubber, etc., Also in it, since it is the same as that of the above especially, a polyamide elastomer or a polyester elastomer is preferred, and a polyester elastomer is more preferred.
[0041]Although construction material of the outer tube 5 is usually made the same along with the longitudinal direction, the presentation may change with parts if needed. Generally, objective flexural rigidity is expressed with a product of the rate E of bending flexibility, and section second-moment I. Section second-moment I of a catheter body which is a cylindrical tubular body is determined from outer diameter D_o and inside diameter D_i, and is shown by formula with the one following.
[0042]
[Equation 1]

$$I = \frac{\pi (D_o^4 - D_i^4)}{64}$$

[0043]That is, rigidity also becomes high as outer diameter D_o becomes large, and, so that the difference of outer diameter D_o and inside diameter D_i is [outer diameter D_o] larger in a fixed case. Since the tendency for it to be regulated by the blood circulatory system and technique which apply [in the case of a vessel catheter] the outer diameter and inside diameter of the catheter body 2 in many cases, and for the difference of an outer diameter and an inside diameter to become small experientially is shown, the rigidity of a catheter body becomes low and becomes disadvantageous for bending prevention. Therefore, in order to obtain required and sufficient rigidity, it is preferred to perform material selection on the basis of the rate of bending flexibility of material.
[0044]In this invention, the rigidity of the base 6 and the pars intermedia 7 is mainly pushed in, and influences a sex and torque convectivity.
The most is left to the rigidity of the inner tube 4.
The rigidity of the tip part 8 mainly influences flattery nature and ****** resistance (pressure to the blood vessel crooked especially).
It is equal to the rigidity of the outer tube 5.
And the rigidity of the inner tube 4 and the balance with rigidity of the outer tube 5 influence kink-proof nature greatly. Since it is such, it is required to make flexural rigidity of the inner tube 4 and the outer tube 5 into a proper value, and, specifically, it is preferred to consider it as the following ranges.
[0045]As for the rate of bending flexibility of the inner tube 4 (ASTM D-790, 23 **), it is preferred that they are 1500-15000 kg / cm^2, and it is more preferred that they are 2000-8000 kg / cm^2. If pushing nature and torque convectivity are inferior in this being less than 1500 kg / cm^2 and 15000 kg / cm^2 is exceeded, The conformity over a guide wire worsens and the load to a flexible blood vessel wall increases, and moreover, a rigid difference with the tip part 8 becomes large, and it becomes easy to produce a kink in the boundary part 10.
[0046]As for the rate of bending flexibility of the outer tube 5 and the outer tube 5 especially in the tip part 8 (ASTM D-790, 23 **), it is preferred that they are 5-1500 kg / cm^2, and it is more preferred that they are 300-800 kg / cm^2. The power and torque which are pushed in from the base 6 as this is less than 5 kg / cm^2 become are hard to be transmitted up to the tip 22 neighborhood, The rigid difference of the pars intermedia 7 and the tip part 8 becomes large, if it becomes easy to produce a kink in the boundary part 10 and 1500 kg / cm^2 is exceeded, the conformity over a guide wire will worsen and the stimulus given to a blood vessel wall will become large.
[0047]As for the difference of the rate of bending flexibility of the inner tube 4 and the outer tube 5 (ASTM D-

790, 23 **), it is preferred that they are 100-14000 kg / cm^2 grade, and it is more preferred that they are 100-6000 kg / cm^2 grade. In this Description, the rate of bending flexibility of an inner tube or an outer tube means the rate of bending flexibility of the material which constitutes an inner tube and an outer tube. In this invention, the junction to the inner tube 4 and the outer tube 5, It is made as [stick / the peripheral face of the inner tube 4 and the inner skin of the outer tube 5], and as the method, For example, the method of pasting up the inner tube 4 and the outer tube 5 with adhesives or a solvent, the method of welding the inner tube 4 and the outer tube 5 (for example, thermal melting arrival, high frequency weld), the method of expanding the outer tube 5 with a solvent and inserting the inner tube 4, or the method of forming the inner tube 4 and the outer tube 5 in one by 2 color extrusion molding is mentioned.

[0048]In this invention, although the size in particular of the catheter body 2 is not limited, in the case of the vessel catheter used inserting in a cerebral blood vessel, for example the overall length of the catheter body 2, About 50-200 cm, about 70-150 cm is especially preferred, as for especially the length of the pars intermedia 7, about 10-20 cm is preferred about 5-30 cm, and, as for especially the length of the tip part 8, about 10-20 cm is preferred about 7-35 cm. In such a range, the balance of the flexural rigidity of each part of the catheter body 2 becomes good, and the effect mentioned above is demonstrated effectively. As for the size of the same viewpoint to others in the base 6, the pars intermedia 7, and the tip part 8, it is preferred to consider it as the range shown in the following table 1.

[0049]

[Table 1]

表 1 (単位：mm)

	基部6	中間部7	先端部8
外径	0.6 ～2.0 (0.7 ～1.2)	0.5 ～1.6 ＊ (0.7 ～1.0)	0.3 ～1.0 ＊ (0.6 ～0.9)
内径	0.2 ～1.6 (0.3 ～0.9)	0.2 ～1.3 (0.3 ～0.7)	0.2 ～0.7 ＊ (0.3 ～0.6)
外管厚さ	0.05～0.3 (0.05～0.2)	0.03～0.3 (0.05～0.15)	0.05～ 0.3 (0.05～0.15)
内管厚さ	0.05～0.5 (0.08～0.3)	0.025～0.25＊ (0.01～0.2)	———

かっこ内は、より好ましい範囲を示す
＊印は、平均値を示す

[0050]What the outside surface of the catheter body 2 is covered for with the hydrophilic (or water solubility) polymeric material in this invention (not shown) is preferred. Thereby, when the outside surface of the catheter body 2 contacts blood or a physiological saline, a coefficient of friction decreases, lubricity is given, the slidability of the catheter body 2 improves much more, and, as a result, pushing nature, conformity, kink-proof nature, and safety increase much more. As hydrophilic polymer material, the polymeric material of following nature or composition or its derivative is mentioned.

[0051]The example of a <naturally-ocurring-polymers substance> 1 starch system : Carboxylmethyl starch, The example of dialdehyde starch 2 cellulose type : CMC, MC, HEC, HPC3 tannin, the example:tannin of a NIGUNIN system, the example:alginic acid of a NIGUNIN 4 polysaccharide system, gum arabic, guar gum, tragacanth gum, the example of TAMARINTO kind 5 protein: Gelatin, casein, glue, collagen [0052]example of <synthetic water soluble polymer> 1PVA system: -- example of polyvinyl alcohol 2 polyethylene-oxide system: -- polyethylene oxide. Example of polyethylene-glycol 3 acrylic acid series :. Example of a sodium-polyacrylate 4 maleic-anhydride system :. Example of methyl vinyl ether maleic anhydride copolymer 5 phthalate system :. example of polyhydroxyethyl phthalic ester 6 water soluble polyester: -- example of polydimethyl roll propionate ester 7 ketone aldehyde resin: -- example of methyl-isopropyl-ketone formaldehyde-resins 8 acrylamide system: -- example of polyacrylamide 9 polyvinylpyrrolidone system:. example of PVP10 polyamine system: -- example of polyethyleneimine 11 poly electrolyte: -- the polystyrene sulfonate 12 -- in addition to this -- example: --

water-soluble nylon [0053]But especially A cellulose type polymeric material (for example, hydroxypropylcellulose), [among these] A polyethylene oxide system polymeric material (polyethylene glycol), A maleic anhydride system polymeric material (for example, a maleic anhydride copolymer like a methyl vinyl ether maleic anhydride copolymer), Since a low coefficient of friction is obtained stably, an acrylamide system polymeric material (for example, polyacrylamide) and water-soluble nylon (for example, AQ-nylon P-70 by Toray Industries, Inc.) are preferred. If it is not limited to a water-soluble thing but the above-mentioned water soluble polymer substance is made into basic constitution as a derivative of the above-mentioned polymeric material, there is no restriction in particular, and even if insolubilized, there is flexibility and it should just carry out water to a chain.

[0054]For example, the esterification material obtained by condensation of the above-mentioned polymeric material, addition, substitution, oxidation, a reduction reaction, etc., A salt, an amidation thing, an anhydride, a halogenide, an etherification thing, hydrolyzate, An acetalization thing, a formal ghost, an ARUKI roll ghost, the 4th class ghost, a diazotization thing, A hydrazide ghost, a sulfonation thing, a nitration thing, an ion complex; A diazonium group, An azido group, an isocyanate group, an acid chloride group, an acid anhydride group, an imino carbonic ester group, A bridge construction thing with the substance which has two or more reactive functional groups, such as an amino group, a carboxyl group, an epoxy group, a hydroxyl group, and an ARURAHIDO group; copolymer with a vinyl compound, acrylic acid, methacrylic acid, diene series, a maleic anhydride, etc., etc. are mentioned.

[0055]In order to fix such an enveloping layer of hydrophilic polymer material to the outside surface of the catheter body 2, it is preferred to carry out by carrying out a covalent bond to the reactive functional group existed or introduced into the inside of the outer tube 5 or the surface of the outer tube 5. Thereby, the continuous lubricative surface can be obtained. The reactive functional group existed or introduced into the inside of the outer tube 5 or the surface, As long as it reacts to said polymeric material, it joins together thru/or constructs a bridge and it fixes, what kind of thing may be used, A diazonium group, an azido group, an isocyanate group, an acid chloride group, an acid anhydride group, an imino carbonic ester group, an amino group, a carboxyl group, an epoxy group, a hydroxyl group, an aldehyde group, etc. are mentioned, and an isocyanate group, an amino group, an aldehyde group, and an epoxy group are especially preferred.

[0056]Although the average molecular weight in particular of the hydrophilic polymer material in this invention is not limited, its about three to 5 million thing is preferred. Thereby, lubricity is high, and it is moderate thickness, and a lubricating layer with a moderate degree of swelling at the time of water is obtained. Especially although the thickness in particular of the lubricating layer by such hydrophilic polymer material is not limited, it is preferred to be referred to as about 1-30 micrometers about 0.1-100 micrometers. What is indicated to JP,53-106778,A, US,4100309,B, JP,60-259269,A, and JP,1-33181,B is applicable to the presentation and coating method of hydrophilic polymer material in this invention, for example.

[0057]

[Example]Hereafter, concrete working example of this invention is described.

(EXAMPLE) The Plastic solid of the inner tube 4 was manufactured by the polyamide elastomer which is a copolymer of polypropylene oxide and Nylon 610, on the other hand, the Plastic solid of the outer tube 5 was manufactured by the polyester elastomer which is a copolymer of polytetramethylene oxide and polybutylene terephthalate, said inner tube 4 was inserted into this outer tube 5, these were welded, and the catheter body 2 of the structure shown in drawing 2 was produced.

[0058]The rates of bending flexibility of said inner tube 4 (ASTMD-790, 23 **) were 5000 kg / cm^2, and the rates of bending flexibility of said outer tube 5 (ASTM D-790, 23 **) were 720 kg / cm^2. Next, the enveloping layer of the methyl vinyl ether maleic anhydride copolymer which is hydrophilic polymer material mostly in the whole region of the outside surface of said catheter body 2 is formed by the method indicated to JP,1-33181,B. Then, the end face 21 of the catheter body was equipped with the hub 11, and the vessel catheter of this invention was obtained.

[0059]The size of each part of the catheter body 2 is as follows.

Catheter body overall length : 150-cm base length . : 110-cm base outer diameter : 1.1-mm base inside diameter . : 0.65-mm pars intermedia length: -- 20-cm pars intermedia outer diameter: -- 1.1 mm to 0.90 mm -- gradual decrease pars intermedia inside diameter: -- 0.65-mm tip part length: -- 20-cm tip part outer diameter: -- 0.90 mm to 0.74 mm -- gradual decrease tip part inside diameter: -- gradually decrease from 0.65 mm to 0.54 mm [0060](Comparative example) Manufacture the Plastic solid of the inner tube 14 with polypropylene, on the other hand, manufacture the Plastic solid of the outer tube 15 with an ethylene-vinylacetate copolymer, insert said inner tube 14 into this outer tube 15, and these are welded, The catheter body 12 in which the base 16 as

shown in drawing 3 comprised a double tube, and the tip part 18 comprised only the outer tube 5 was produced. This catheter body 12 does not have a portion equivalent to pars intermedia. Next, the end face of this catheter body 12 was equipped with the same hub 11 as said working example, and vessel catheter 1' of the comparative example was obtained.

[0061]The size of each part of the catheter body 12 is as follows.

catheter body overall-length: -- 146-cm base length : 128-cm base outer diameter : 0.94-mm base inside diameter : 0.61-mm tip part length: -- 18-cm tip part outer diameter: -- 0.74-mm tip part outer diameter: -- 0.54 mm [0062][Experiment 1] In order to investigate kink-proof nature to the vessel catheter of above-mentioned working example and a comparative example, the following bending examinations were done. In a cylindrical adjustment catch, insert a catheter body to the position of the abbreviation half length of the pars intermedia, and it fixes, on the other hand, a wire in the lumen of a catheter body from the tip side of a catheter body to the position of the length for the minute of a tip part half [about], [insert and] In underwater [37 **], the wire was gradually moved so that the end face might draw an arc centering on the tip (lumen inside), and the angle theta of the axis of a base when a crease arises on the boundary between pars intermedia and a tip part, and the axis of a tip part to make was measured (five measurement counts).

[0063]To being theta= 71.0 degrees, with the vessel catheter of the above-mentioned comparative example, it is theta= 64.1 degrees and the result checked that the vessel catheter of this invention was excellent in kink-proof nature with the vessel catheter of working example of above-mentioned this invention.

[0064][Experiment 2] The following animal experiments were conducted using the vessel catheter of above-mentioned working example and a comparative example, and the operativity of the vessel catheter was investigated. In the lumen of a catheter, where a guide wire is inserted in, from the carotid artery of the rabbit, the catheter body was inserted and the tip was introduced to the peripheral part of a mesenteric artery through the abdominal aorta. The blood vessel was chosen in the tee of a blood vessel, combining suitably the attitude of a guide wire, the attitude of a catheter, and rotation.

[0065]In the vessel catheter of working example of above-mentioned this invention, friction with a blood vessel is small, pushing nature and the torque convectivity in the case of rotation are very good, the flattery nature to the selectivity and the guide wire of a blood vessel in a tee also has them, and such an effect was especially demonstrated also in the peripheral vessel of a narrow diameter. [good] Since it was such, operation of catheter implantation was easy and time until the tip of a catheter reaches to a target part was also a short time (about 5 minutes).

[0066]On the other hand, in the vessel catheter of the above-mentioned comparative example, it is in pushing nature and torque convectivity about a problem, selection of the blood vessel in a tee took time and effort, the flattery nature to a guide wire was also inferior, and such a fault was remarkable in the peripheral vessel of a narrow diameter especially. Therefore, time until the tip of a catheter reaches operation of catheter implantation to a target part with difficulty was also a long time (about 15 minutes) compared with said this invention.

[0067]

[Effect of the Invention]As stated above, according to the vessel catheter of this invention, a rigid inner tube with a high main part of a catheter body, Comprise a double tube which combined the rigid low outer tube compared with this, and the portion of this double tube, Comprise a base where the outer diameter of a catheter body is almost constant to a longitudinal direction, and pars intermedia which the outer diameter of a catheter body dwindles toward the direction of a tip, and from pars intermedia further the tip part by the side of a tip, Since it comprises a flexible outer tube which an outer diameter dwindles, pushing nature, torque convectivity, the conformity over the guide wire inserted in the crooked blood vessel, kink-proof nature, and the selectivity in vascular bifurcation improve, and there are few stimuli to a blood vessel, damage to a blood vessel wall is prevented, and safety is also high.

[0068]Since blood etc. are contacted, formation is carried out in the lubricous surface and frictional resistance decreases when the outside surface of a catheter body is covered with hydrophilic polymer material, the above-mentioned effect increases much more. Not to mention the usual artery and vein whose path is comparatively large, a path like a cerebral blood vessel or other peripheral vessels is small, and the effect of such this invention has much branching, and also when inserting selectively into the blood vessel which carried out crookedness meandering, it is demonstrated effectively, for example.

[Translation done.]

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TECHNICAL FIELD

[Industrial Application]This invention relates to the vessel catheter used for superselective pouring of drugs, such as an intravascular operation and an anticancer drug, angiography, etc.

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PRIOR ART

[Description of the Prior Art]In recent years, a surgical operation is not conducted but the intravascular operation which treats the lesions (an aneurysm, an arteriovenous malformation tumor, etc.) which inserted the catheter into the blood vessel endermically and were rich in vascular lesion and a blood vessel prospers. In such technique, crookedness meandering must be carried out intricately and a vessel catheter must be selectively inserted in the specific part of a thin blood circulatory system with much branching.

[0003]For example, in the intravascular operation called the plug way given to an aneurysm, an arteriovenous malformation tumor, etc. which are looked at by the cerebral blood vessel etc. The tip of a thin vessel catheter is selectively inserted to the affected part within a brain, or its neighborhood, A coil is poured into granular plug substances, such as liquefied plug substances, such as a dimethylsulfoxide solution of cyanoacrylate and an ethylene-vinylalcohol copolymer, and granulation of polyvinyl alcohol, and it from the tip of a vessel catheter. Thus, the vessel catheter of a narrow diameter according to it is used for administration of the drugs to a thin blood vessel, or pouring of a contrast medium.

[0004]Therefore, to the vessel catheter of such a narrow diameter. To chemical and biosafety [which are required of the usual vessel catheter], in addition, in order to require the operativity which can be inserted in the blood circulatory system of a thin complicated pattern with quick and positive selectivity and to pour in further the plug substance mentioned above, Chemical resistance, the solvent resistance which does not produce deterioration when especially solvents, such as dimethyl sulfoxide, are contacted, etc. are required.

[0005]What is called pushing nature which the power which a way person pushes in may be certainly delivered to the tip side from the end face side of a catheter in order to make the inside of a blood vessel insert in when the above-mentioned operativity of a vessel catheter is explained in full detail, The torque convectivity which the torque applied in the end face side of a catheter may be certainly delivered to the tip side, with the conformity (the following and "the conformity over a guide wire" -- or it is only called "flattery nature") which can progress without damaging a blood vessel wall smoothly along with the guide wire in which the inside of the crooked blood vessel was inserted beforehand. Also after a catheter tip's reaching to the target place and drawing out a guide wire, the kink-proof nature which bending does not produce is needed for a catheter by the curve of a blood vessel, and the crooked part. The lubricity (slidability by reduction of a coefficient of friction) of the outside surface of a catheter is needed as one of the greatest factors that give these character to a catheter.

[0006]Among these, as conventional technology for giving pushing nature and the conformity over a guide wire, The vessel catheter which comprised a comparatively softness outer tube which has the portion which covered the outside surface of a comparatively hard inner tube and this inner tube, and was projected from the tip of the inner tube and whose main long part is double tube structure is developed and used. In such a vessel catheter, the thing of the following combination is proposed as that of the component of an inner tube and an outer tube.

[0007]In the real table No. 500013 [Showa 60 to], and the correspondence U.S. Pat. No. 4385635 item, polyamide is used for an inner tube, and urethane is used for an outer tube, and the vessel catheter formed in tapered shape so that the inside diameter might increase the tip end part of an inner tube gradually is indicated. However, in this vessel catheter, since an outer tube is a product made from urethane, it is lacking in said solvent resistance, and is not suitable for the catheter used for a plug way.

[0008]In this device, since rigidity changes from a part for the double tube part of polyamide and urethane rapidly in the boundary part which shifts to a part for 1-fold tube part of urethane, a catheter body also has the fault of being easy to produce bending (kink). In particular, in a part for 1-fold tube part of urethane, an outer diameter and an inside diameter are constant, since rigidity is not gradually decreasing toward a tip, it is the cause by which stress concentration arises from a double tube in the boundary part which shifts to one detonator, and this produces a kink, and flattery nature is also inferior. repeating intravascular operation especially -- a line -- to inside, due to construction material fatigue, in being excessive, a report that the boundary part which shifts to one detonator cut from the double tube appears here and there.

[0009]In JP,62-17082,Y, silicone rubber is used for an outer tube and the vessel catheter using the hard resin chosen as the inner tube from polyethylene, polypropylene, a fluoro-resin, and hard vinylchloride resin is indicated. In [although there is solvent resistance in this vessel catheter (except for hard vinylchloride resin)] the boundary part of the portion (body part 4) of a double tube, and the portion (tip part 3) of one detonator, Since the level difference equivalent to the thickness of an inner tube is formed in the tube lumen, it is easy to produce bending in this portion, and said kink-proof nature is inferior. Kink-proof nature is inferior similarly about combination in recent years in the inner tube made from polypropylene put in practical use, and the outer tube made from an ethylene-vinylacetate copolymer.
[0010]In JP,59-156353,A, the tubular body by the side of the base made of nylon and the tip part made from a polyether polyamide copolymer are united, and the vessel catheter which marked the pliability of the tip part moderately is indicated. However, this vessel catheter is not what makes double pipe construction, Since it is what unites and connects a dissimilar material, there are fear of cutting in a fusion part and a possibility of a level difference being formed in an outside surface and doing damage to a blood vessel wall at the time of catheter implantation, and there is a fault that the still more nearly special manufacturing installation for fusion of polymer must be used.
[0011]In the U.S. Pat. No. 4636346 item, the guiding catheter which has the principal part of 3-fold tube structure and a tip part of the double tube structure (the interlayer of the principal part is lacked) extended in the direction of a tip from it is indicated. Since this catheter is a catheter for the guide for inserting other catheters in that lumen (lumen), and deriving to a target part, let it be a premise to take the inside diameter of a lumen as greatly as possible.
Therefore, it is difficult to apply to the vessel catheter of the narrow diameter mentioned above as a matter of fact.

[0012]Since each vessel catheter which was mentioned above was lacking in the lubricity of the outside surface and inferior to the slidability within a blood vessel, it was difficult for it to make a vessel catheter arrive at a target part safely for a short time.

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EFFECT OF THE INVENTION

[Effect of the Invention]As stated above, according to the vessel catheter of this invention, a rigid inner tube with a high main part of a catheter body, Comprise a double tube which combined the rigid low outer tube compared with this, and the portion of this double tube, Comprise a base where the outer diameter of a catheter body is almost constant to a longitudinal direction, and pars intermedia which the outer diameter of a catheter body dwindles toward the direction of a tip, and from pars intermedia further the tip part by the side of a tip, Since it comprises a flexible outer tube which an outer diameter dwindles, pushing nature, torque convectivity, the conformity over the guide wire inserted in the crooked blood vessel, kink-proof nature, and the selectivity in vascular bifurcation improve, and there are few stimuli to a blood vessel, damage to a blood vessel wall is prevented, and safety is also high.
[0068]Since blood etc. are contacted, formation is carried out in the lubricous surface and frictional resistance decreases when the outside surface of a catheter body is covered with hydrophilic polymer material, the above-mentioned effect increases much more. Not to mention the usual artery and vein whose path is comparatively large, a path like a cerebral blood vessel or other peripheral vessels is small, and the effect of such this invention has much branching, and also when inserting selectively into the blood vessel which carried out crookedness meandering, it is demonstrated effectively, for example.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]The purpose of this invention is excellent in operativity, such as pushing nature, conformity, kink-proof nature, and there is little vascular injury, it is excellent in safety, and there is in providing a vessel catheter suitable also for the technique especially to the blood vessel of a narrow diameter.

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MEANS

[Means for Solving the Problem]Such a purpose is attained by this invention of following the (1) - (8).
[0015](1) Double tube structure which consists of an inner tube and an outer tube stuck to an outside surface of this inner tube is made, Have the catheter body in which it applied at a tip from a end face, and a lumen was formed in an inside, and from a rate of bending flexibility of said outer tube, a rate of bending flexibility of said inner tube is a large vessel catheter, and said catheter body, A base where an outer diameter is almost constant to a longitudinal direction, and becomes it from said inner tube and said outer tube, Pars intermedia which consists of said inner tube which it is extended toward the direction of a tip of a catheter body from a tip of this base, and the outer diameter dwindles toward the direction of a tip at least, and said outer tube, It is extended toward the direction of a tip of a catheter body from a tip of this pars intermedia, and comprises a tip part which consists of said outer tube which the outer diameter dwindles toward the direction of a tip, Near the boundary part of said base and said pars intermedia, and in [apply to said tip part from said pars intermedia, and the flexural rigidity of a catheter body gradually decreases, and] near the boundary part of said pars intermedia and said tip part, A vessel catheter currently forming the smooth surface where an outside surface of a catheter body continued, respectively.
[0016](2) A vessel catheter given in the above (1) which an outer diameter of said inner tube in said pars intermedia dwindles toward the direction of a tip.
[0017](3) A vessel catheter the above (1) which thickness of said outer tube in said tip part dwindles toward the direction of a tip, or given in (2).
[0018](4) A vessel catheter the above (1) whose rates of bending flexibility of said inner tube (ASTM D-790, 23 **) are 1500-15000 kg / cm^2 thru/or given in either of (3).
[0019](5) A vessel catheter the above (1) by which said inner tube is constituted from a polyamide elastomer thru/or given in either of (4).
[0020](6) A vessel catheter the above (1) whose rates of bending flexibility of said outer tube in said tip part (ASTM D-790, 23 **) are 5-1500 kg / cm^2 thru/or given in either of (5).
[0021](7) A vessel catheter the above (1) by which said outer tube is constituted from a polyester elastomer thru/or given in either of (6).
[0022](8) A vessel catheter the above (1) with which an outside surface of said catheter body is covered with hydrophilic polymer material thru/or given in either of (7).

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OPERATION

[Function]The vessel catheter of this invention A rigid inner tube with a high main part of a catheter body, Since it comprises a double tube which combined the rigid low outer tube compared with this, an outer tube carries out predetermined length projection from the tip of an inner tube further and the flexible catheter tip part is formed, Not to mention the usual artery and vein whose path is comparatively large, pushing nature, conformity, and kink-proof nature outstanding in a detailed and complicated blood vessel like a cerebral blood vessel or other peripheral vessels, for example are demonstrated, it has positive selectivity in vascular bifurcation, and safety is also still higher.

[0024]When it furthermore explains in full detail, in the vessel catheter of this invention the portion of double tube structure, It comprises a base where the outer diameter of a catheter body is almost constant to a longitudinal direction, and pars intermedia which the outer diameter of a catheter body dwindles toward the direction of a tip, Comprise only an outer tube more flexible than pars intermedia to the tip side, and since the tip part which an outer diameter dwindles toward the direction of a tip is formed, it applies to pars intermedia from a base, The outstanding pushing nature and torque convectivity are demonstrated, it applies to a tip part from pars intermedia, the outstanding conformity over the guide wire inserted in the blood vessel crooked since the rigidity of the catheter body decreased continuously over the whole region mostly is demonstrated, and also bending (kink) is prevented.

[0025]In this case, in pars intermedia and a tip part, since the outer diameter is gradually decreasing toward the direction of a tip, the insertion nature at the time of pushing in a catheter in a blood vessel (performance traverse) and the selectivity in vascular bifurcation are high. In the boundary part of a base and pars intermedia, and the boundary part of pars intermedia and a tip part, since the outside surface of a catheter body forms the continuous smooth surface without a level difference, respectively, there are few stimuli to a blood vessel and they do not do damage.

[0026]So that the outer diameter of the inner tube in pars intermedia may gradually decrease toward the direction of a tip, That is, the rigid abrupt change and stress concentration in said boundary part are lost, and it becomes difficult to produce a kink by forming the outside surface of an inner tube in tapered shape by adjusting appropriately the elastic modulus of an inner tube and an outer tube with selection of material or a size again. Since rigidity is comparatively high near a room temperature, and especially the inner tube that comprised a polyamide elastomer or a polyester elastomer is excellent in pushing nature and becomes flexible near body temperature, it adapts itself to crookedness of a blood vessel well, and flattery nature and kink-proof nature increase further.

[0027]Safety increases much more, without contacting blood etc., carrying out formation in the lubricous surface, and the operativity within a blood vessel improving further, and damaging a blood vessel wall, when the outside surface of a catheter body is covered with hydrophilic polymer material.

[0028]

[Elements of the Invention]Hereafter, this invention is explained in detail based on a good example shown in an accompanying drawing. A top view in which drawing 1 shows an example of an entire configuration of a vessel catheter of this invention, and drawing 2 are drawings of longitudinal section expanding and showing composition near the tip part of a vessel catheter shown in drawing 1. By drawing 2, in order to understand easily, especially a diameter direction of a vessel catheter is expanded and it is shown typically.

[0029]As shown in drawing 1, the vessel catheter 1 of this invention comprises the catheter body 2 and the hub 11 with which the end face 21 of this catheter body 2 was equipped. The lumen 3 is formed in an inside, covering the catheter body 2 at the tip 22 from the end face 21. This lumen 3 serves as channels, such as a drug solution.

At the time of insertion in a blood vessel of the vessel catheter 1, a guide wire is inserted in in the lumen 3. The hub 11 functions also as a grasping part at the time of functioning as inlets, such as a drug solution into the

lumen 3, and a loading slot of said guide wire, and operating the vessel catheter 1.
[0030]As shown in drawing 2, double tube structure which consists of the outer tube 5 which the catheter body 2 was stuck to the main part on an outside surface of the inner tube 4 and this inner tube 4, and was joined is made. The inner tube 4 comprises a rigid large material comparatively.
The outer tube 5 comprises a comparatively flexible material.
The catheter body 2 comprises the base 6, the pars intermedia 7, and the tip part 8 sequentially from the end face 21 side. Among these, the base 6 and the pars intermedia 7 are making said double tube structure, and the tip part 8 comprises only the outer tube 5.
[0031]In the base 6, an outer diameter of the catheter body 2 is almost constant to a catheter longitudinal direction. It is preferred that an inside diameter (diameter of the lumen 3) of the catheter body 2 is almost constant similarly.
[0032]In the pars intermedia 7, an outer diameter of the catheter body 2 is gradually decreasing toward the direction of the tip 22 (henceforth the direction of a tip). In the pars intermedia 7, it is preferred that an outer diameter of the inner tube 4 gradually decreases toward the direction of a tip, and, as for an inside diameter of the catheter body 2, it is still more preferred that it is almost fixed to a longitudinal direction. Thereby, thickness of the inner tube 4 becomes thin gradually toward the direction of a tip, and the rigidity also decreases continuously.
[0033]The inner tube 4 lacks and the tip part 8 comprises only the outer tube 5. In this tip part 8, an outer diameter of the catheter body 2 is gradually decreasing toward the direction of a tip. thickness of the outer tube 5 like a graphic display, in the tip part 8, in order to make regularity or its percentage reduction low for a diameter of the lumen 3 and to improve the insertion nature of a guide wire although it may be about 1 law at a catheter longitudinal direction, It is preferred that the outer-tube 5 whole region or a part of thickness gradually decrease toward the direction of a tip. It is advantageous also to decreasing the rigidity of the tip part 8 continuously in the direction of a tip to have such composition, and it is preferred also for improvement in conformity and safety.
[0034]As it is indicated in drawing 2 as a cone angle of an outside surface of the catheter body 2 in the pars intermedia 7, and a cone angle of an outside surface of the catheter body 2 in the tip part 8, it may be the same or may differ. In the boundary part 9 of the base 6 and the pars intermedia 7, the smooth surface (for example, field which curves to a catheter longitudinal direction) where an outside surface of the catheter body 2 continued is formed, and a level difference is not formed substantially. The boundary part 9 is prevented also from that there are few stimuli to a blood vessel and they also do damage to a blood vessel wall on the occasion of catheter implantation by this, and being prevented, being caught when passing through a loading slot of a catheter implantation instrument like a sheath moreover, and wearing out.
[0035]Also in the boundary part 10 of the pars intermedia 7 and the tip part 8, since an outside surface of the catheter body 2 forms a successive surface and a level difference is not formed similarly, the same effect as the above is acquired. When a cone angle of an outside surface of the catheter body 2 in the pars intermedia 7 differs from a cone angle of an outside surface of the catheter body 2 in the tip part 8, It is preferred that an outside surface of the catheter body 2 in the boundary part 10 forms the continuous smooth surface like said boundary part 9.
[0036]As a component of the inner tube 4, for example Polyolefines, such as polypropylene and polyethylene, Polyester, such as polyamide, polyethylene terephthalate, and polybutylene terephthalate, Fluororesin, such as polyurethane, polyvinyl chloride, polystyrene system resin, and an ethylene-tetrafluoroethylene copolymer, Although it is usable in resin which has various flexibility, such as polyimide, and various elastomers, such as a polyamide elastomer, a polyester elastomer, and a polyurethane elastomer, Also especially in it, a polyamide elastomer or a polyester elastomer is preferred, and a polyamide elastomer is more preferred. By using such a material, rate of bending flexibility optimal as the inner tube 4 is obtained, and solvent resistance is high, and it excels in kink-proof nature etc. Since rigidity is comparatively high near a room temperature, and a polyamide elastomer and a polyester elastomer are excellent in pushing nature or torque convectivity and become flexible near body temperature, after inserting in the inside of the body, it gets used better in crookedness of a blood vessel, and flattery nature and kink-proof nature increase further.
[0037]With a polyamide elastomer, here, for example Nylon 6, the nylon 64, Nylon 66, Nylon 610, Nylon 612, Nylon 46, the nylon 9, NANAIRON 11, Nylon 12, N-alkoxy methyl denaturation nylon, Various aliphatic series or aromatic polyamide like hexamethylenediamine isophthalic acid polycondensation polymer and METAKISHI roil diamine adipic acid polycondensation polymer is used as a hard segment, A block copolymer which uses polymer, such as polyester and polyether, as a soft segment is typical, In addition, they are polymer alloys (a polymer blend, graft polymerization, random polymerization, etc.) of said polyamide and resin which is rich in pliability, a thing which elasticity-ized said polyamide with a plasticizer etc., and a concept also containing these mixtures

further.
[0038]As for said plasticizer, it is preferred to use what is hard to be extracted in a solvent, blood, etc. With a polyester elastomer, saturated polyester, such as polyethylene terephthalate and polybutylene terephthalate, A block copolymer with polyether or polyester is typical, in addition are what elasticity-ized these polymer alloys and said saturated polyester with a plasticizer etc., and a concept also containing these mixtures further.
[0039]Various additives, such as an alloy-ized agent, a compatibilizer, a hardening agent, a softener, a contrast medium, stabilizer, and colorant, may be blended with said polyamide elastomer or a polyester elastomer if needed. In this case, it is preferred that an addition ingredient uses what is hard to be extracted in a solvent, a drug solution, blood, etc. Although construction material of the inner tube 4 is usually made the same along with the longitudinal direction, the presentation may change with parts if needed.
[0040]As a component of the outer tube 5, they are polypropylene and polyethylene (especially), for example. Polyolefines, such as low density polyethylene and an ethylene-vinylacetate copolymer, Although it is usable in resin and an elastomer which are rich in the various pliability of said polyamide elastomer, said polyester elastomer, a polyurethane elastomer, soft polyvinyl chloride, a polystyrene elastomer, a fluorinated elastomer, silicone rubber, latex rubber, etc., Also in it, since it is the same as that of the above especially, a polyamide elastomer or a polyester elastomer is preferred, and a polyester elastomer is more preferred.
[0041]Although construction material of the outer tube 5 is usually made the same along with the longitudinal direction, the presentation may change with parts if needed. Generally, objective flexural rigidity is expressed with a product of the rate E of bending flexibility, and section second-moment I. Section second-moment I of a catheter body which is a cylindrical tubular body is determined from outer diameter D_o and inside diameter D_i, and is shown by formula with the one following.
[0042]
[Equation 1]

$$I = \frac{\pi (D_o^4 - D_i^4)}{64}$$

[0043]That is, rigidity also becomes high as outer diameter D_o becomes large, and, so that the difference of outer diameter D_o and inside diameter D_i is [outer diameter D_o] larger in a fixed case. Since the tendency for it to be regulated by the blood circulatory system and technique which apply [in the case of a vessel catheter] the outer diameter and inside diameter of the catheter body 2 in many cases, and for the difference of an outer diameter and an inside diameter to become small experientially is shown, the rigidity of a catheter body becomes low and becomes disadvantageous for bending prevention. Therefore, in order to obtain required and sufficient rigidity, it is preferred to perform material selection on the basis of the rate of bending flexibility of material.
[0044]In this invention, the rigidity of the base 6 and the pars intermedia 7 is mainly pushed in, and influences a sex and torque convectivity.
The most is left to the rigidity of the inner tube 4.
The rigidity of the tip part 8 mainly influences flattery nature and ****** resistance (pressure to the blood vessel crooked especially).
It is equal to the rigidity of the outer tube 5.
And the rigidity of the inner tube 4 and the balance with rigidity of the outer tube 5 influence kink-proof nature greatly. Since it is such, it is required to make flexural rigidity of the inner tube 4 and the outer tube 5 into a proper value, and, specifically, it is preferred to consider it as the following ranges.
[0045]As for the rate of bending flexibility of the inner tube 4 (ASTM D-790, 23 **), it is preferred that they are 1500-15000 kg / cm^2, and it is more preferred that they are 2000-8000 kg / cm^2. If pushing nature and torque convectivity are inferior in this being less than 1500 kg / cm^2 and 15000 kg / cm^2 is exceeded, The conformity over a guide wire worsens and the load to a flexible blood vessel wall increases, and moreover, a rigid difference with the tip part 8 becomes large, and it becomes easy to produce a kink in the boundary part 10.
[0046]As for the rate of bending flexibility of the outer tube 5 and the outer tube 5 especially in the tip part 8 (ASTM D-790, 23 **), it is preferred that they are 5-1500 kg / cm^2, and it is more preferred that they are 300-800 kg / cm^2. The power and torque which are pushed in from the base 6 as this is less than 5 kg / cm^2 become are hard to be transmitted up to the tip 22 neighborhood, The rigid difference of the pars intermedia 7 and the tip part 8 becomes large, if it becomes easy to produce a kink in the boundary part 10 and 1500 kg / cm^2 is exceeded, the conformity over a guide wire will worsen and the stimulus given to a blood vessel wall will become large.

[0047]As for the difference of the rate of bending flexibility of the inner tube 4 and the outer tube 5 (ASTM D-790, 23 **), it is preferred that they are 100-14000 kg / cm^2 grade, and it is more preferred that they are 100-6000 kg / cm^2 grade. In this Description, the rate of bending flexibility of an inner tube or an outer tube means the rate of bending flexibility of the material which constitutes an inner tube and an outer tube. In this invention, the junction to the inner tube 4 and the outer tube 5, It is made as [stick / the peripheral face of the inner tube 4 and the inner skin of the outer tube 5], and as the method, For example, the method of pasting up the inner tube 4 and the outer tube 5 with adhesives or a solvent, the method of welding the inner tube 4 and the outer tube 5 (for example, thermal melting arrival, high frequency weld), the method of expanding the outer tube 5 with a solvent and inserting the inner tube 4, or the method of forming the inner tube 4 and the outer tube 5 in one by 2 color extrusion molding is mentioned.

[0048]In this invention, although the size in particular of the catheter body 2 is not limited, in the case of the vessel catheter used inserting in a cerebral blood vessel, for example the overall length of the catheter body 2, About 50-200 cm, about 70-150 cm is especially preferred, as for especially the length of the pars intermedia 7, about 10-20 cm is preferred about 5-30 cm, and, as for especially the length of the tip part 8, about 10-20 cm is preferred about 7-35 cm. In such a range, the balance of the flexural rigidity of each part of the catheter body 2 becomes good, and the effect mentioned above is demonstrated effectively. As for the size of the same viewpoint to others in the base 6, the pars intermedia 7, and the tip part 8, it is preferred to consider it as the range shown in the following table 1.

[0049]

[Table 1]

表　1　　(単位：mm)

	基部6	中間部7	先端部8
外　径	0.6 ～2.0 (0.7 ～1.2)	0.5 ～1.6 ＊ (0.7 ～1.0)	0.3 ～1.0 ＊ (0.6 ～0.9)
内　径	0.2 ～1.6 (0.3 ～0.9)	0.2 ～1.3 (0.3 ～0.7)	0.2 ～0.7 ＊ (0.3 ～0.6)
外管厚さ	0.05～0.3 (0.05～0.2)	0.03～0.3 (0.05～0.15)	0.05～ 0.3 (0.05～0.15)
内管厚さ	0.05～0.5 (0.08～0.3)	0.025～0.25＊ (0.01～0.2)	———

かっこ内は、より好ましい範囲を示す
＊印は、平均値を示す

[0050]What the outside surface of the catheter body 2 is covered for with the hydrophilic (or water solubility) polymeric material in this invention (not shown) is preferred. Thereby, when the outside surface of the catheter body 2 contacts blood or a physiological saline, a coefficient of friction decreases, lubricity is given, the slidability of the catheter body 2 improves much more, and, as a result, pushing nature, conformity, kink-proof nature, and safety increase much more. As hydrophilic polymer material, the polymeric material of following nature or composition or its derivative is mentioned.

[0051]The example of a <naturally-ocurring-polymers substance> 1 starch system : Carboxylmethyl starch, The example of dialdehyde starch 2 cellulose type : CMC, MC, HEC, HPC3 tannin, the example:tannin of a NIGUNIN system, the example:alginic acid of a NIGUNIN 4 polysaccharide system, gum arabic, guar gum, tragacanth gum, the example of TAMARINTO kind 5 protein: Gelatin, casein, glue, collagen [0052]example of <synthetic water soluble polymer> 1PVA system: -- example of polyvinyl alcohol 2 polyethylene-oxide system: -- polyethylene oxide. Example of polyethylene-glycol 3 acrylic acid series :. Example of a sodium-polyacrylate 4 maleic-anhydride system :. Example of methyl vinyl ether maleic anhydride copolymer 5 phthalate system :. example of polyhydroxyethyl phthalic ester 6 water soluble polyester: -- example of polydimethyl roll propionate ester 7 ketone aldehyde resin: -- example of methyl-isopropyl-ketone formaldehyde-resins 8 acrylamide system: -- example of polyacrylamide 9 polyvinylpyrrolidone system:. example of PVP10 polyamine system: -- example of

polyethyleneimine 11 poly electrolyte: -- the polystyrene sulfonate 12 -- in addition to this -- example: -- water-soluble nylon [0053]But especially A cellulose type polymeric material (for example, hydroxypropylcellulose), [among these] A polyethylene oxide system polymeric material (polyethylene glycol), A maleic anhydride system polymeric material (for example, a maleic anhydride copolymer like a methyl vinyl ether maleic anhydride copolymer), Since a low coefficient of friction is obtained stably, an acrylamide system polymeric material (for example, polyacrylamide) and water-soluble nylon (for example, AQ-nylon P-70 by Toray Industries, Inc.) are preferred. If it is not limited to a water-soluble thing but the above-mentioned water soluble polymer substance is made into basic constitution as a derivative of the above-mentioned polymeric material, there is no restriction in particular, and even if insolubilized, there is flexibility and it should just carry out water to a chain.

[0054]For example, the esterification material obtained by condensation of the above-mentioned polymeric material, addition, substitution, oxidation, a reduction reaction, etc., A salt, an amidation thing, an anhydride, a halogenide, an etherification thing, hydrolyzate, An acetalization thing, a formal ghost, an ARUKI roll ghost, the 4th class ghost, a diazotization thing, A hydrazide ghost, a sulfonation thing, a nitration thing, an ion complex; A diazonium group, An azido group, an isocyanate group, an acid chloride group, an acid anhydride group, an imino carbonic ester group, A bridge construction thing with the substance which has two or more reactive functional groups, such as an amino group, a carboxyl group, an epoxy group, a hydroxyl group, and an ARURAHIDO group; copolymer with a vinyl compound, acrylic acid, methacrylic acid, diene series, a maleic anhydride, etc., etc. are mentioned.

[0055]In order to fix such an enveloping layer of hydrophilic polymer material to the outside surface of the catheter body 2, it is preferred to carry out by carrying out a covalent bond to the reactive functional group existed or introduced into the inside of the outer tube 5 or the surface of the outer tube 5. Thereby, the continuous lubricative surface can be obtained. The reactive functional group existed or introduced into the inside of the outer tube 5 or the surface, As long as it reacts to said polymeric material, it joins together thru/or constructs a bridge and it fixes, what kind of thing may be used, A diazonium group, an azido group, an isocyanate group, an acid chloride group, an acid anhydride group, an imino carbonic ester group, an amino group, a carboxyl group, an epoxy group, a hydroxyl group, an aldehyde group, etc. are mentioned, and an isocyanate group, an amino group, an aldehyde group, and an epoxy group are especially preferred.

[0056]Although the average molecular weight in particular of the hydrophilic polymer material in this invention is not limited, its about three to 5 million thing is preferred. Thereby, lubricity is high, and it is moderate thickness, and a lubricating layer with a moderate degree of swelling at the time of water is obtained. Especially although the thickness in particular of the lubricating layer by such hydrophilic polymer material is not limited, it is preferred to be referred to as about 1-30 micrometers about 0.1-100 micrometers. What is indicated to JP,53-106778,A, US,4100309,B, JP,60-259269,A, and JP,1-33181,B is applicable to the presentation and coating method of hydrophilic polymer material in this invention, for example.

[Translation done.]

* NOTICES *

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EXAMPLE

[Example]Hereafter, concrete working example of this invention is described.

[Translation done.]

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1]It is a top view showing the example of composition of the vessel catheter of this invention.
[Drawing 2]It is drawing of longitudinal section which expands the composition near the tip part of the vessel catheter shown in drawing 1, and is shown typically.
[Drawing 3]It is drawing of longitudinal section which expands the composition near the tip part of the vessel catheter of a comparative example, and is shown typically.
[Description of Notations]
1 Vessel catheter (this invention)
1' vessel catheter (comparative example)
2 Catheter body
21 End face
22 Tip
3 Lumen
4 Inner tube
5 Outer tube
6 Base
7 Pars intermedia
8 Tip part
9 and 10 Boundary part
11 Hub
12 Catheter body
14 Inner tube
15 Outer tube
16 Base
18 Tip part

[Translation done.]

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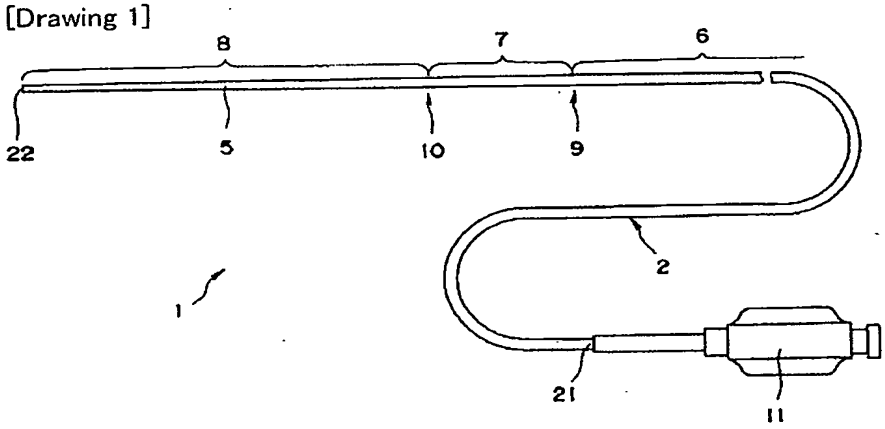
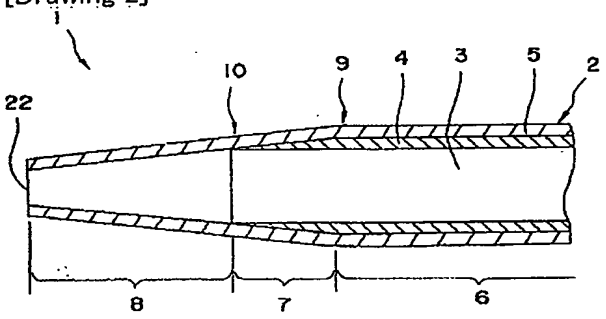
DRAWINGS

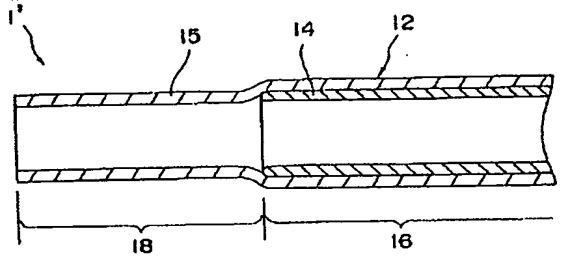
[Drawing 1]



[Drawing 2]



[Drawing 3]



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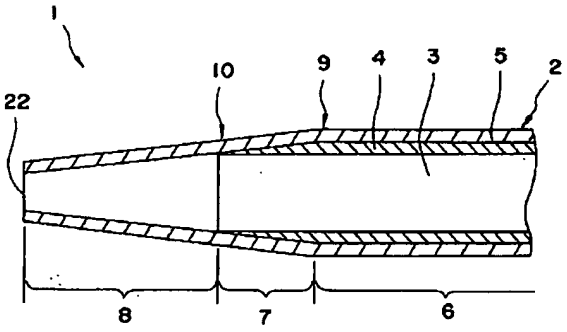
(54)【発明の名称】　血管カテーテル

(57)【要約】

【構成】　本発明の血管カテーテル１はカテーテル本体（以下、「本体」）２を有し、この本体２は、その主要部分が、内管４とその外面に密着する外管５との２重管構造をなし、内管４の曲げ弾性率は外管５のそれより大きい。本体２は、基部６、中間部７および先端部８で構成され、基部６および中間部７は前記２重管構造をなし、先端部８は、外管５のみで構成されている。基部６においては、本体２の外径が長手方向にほぼ一定である。中間部７および先端部８においては、本体２の外径が先端方向に向かって漸減している。基部６と中間部７との境界部９および中間部７と先端部８との境界部１０においては、それぞれ本体２の外表面が連続したなめらかな表面を形成しており、実質的に段差がない。

【効果】　押し込み性、トルク伝達性、血管の屈曲に対する追随性、耐キンク性、血管分岐部における選択性、安全性が向上する。



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【特許請求の範囲】

【請求項１】　内管と該内管の外面に密着する外管とからなる２重管構造をなし、基端から先端にかけて内部に管腔が形成されたカテーテル本体を有し、前記内管の曲げ弾性率が前記外管の曲げ弾性率より大きい血管カテーテルであって、

前記カテーテル本体は、外径が長手方向にほぼ一定で前記内管および前記外管よりなる基部と、該基部の先端からカテーテル本体の先端方向に向かって延長され、少なくともその外径が先端方向に向かって漸減する前記内管および前記外管よりなる中間部と、該中間部の先端からカテーテル本体の先端方向に向って延長され、その外径が先端方向に向かって漸減する前記外管よりなる先端部とで構成され、

前記中間部から前記先端部にかけてカテーテル本体の曲げ剛性が漸減し、前記基部と前記中間部との境界部付近および前記中間部と前記先端部との境界部付近において、それぞれカテーテル本体の外表面が連続したなめらかな表面を形成していることを特徴とする血管カテーテル。

【請求項２】　前記中間部における前記内管の外径が先端方向に向かって漸減する請求項１に記載の血管カテーテル。

【請求項３】　前記先端部における前記外管の厚さが先端方向に向かって漸減する請求項１または２に記載の血管カテーテル。

【請求項４】　前記内管の曲げ弾性率（ＡＳＴＭ　Ｄ－７９０、２３℃）が１５００～１５０００kg/cm^{2}である請求項１ないし３のいずれかに記載の血管カテーテル。

【請求項５】　前記内管がポリアミドエラストマーで構成されている請求項１ないし４のいずれかに記載の血管カテーテル。

【請求項６】　前記先端部における前記外管の曲げ弾性率（ＡＳＴＭ　Ｄ－７９０、２３℃）が５～１５００kg/cm^{2}である請求項１ないし５のいずれかに記載の血管カテーテル。

【請求項７】　前記外管がポリエステルエラストマーで構成されている請求項１ないし６のいずれかに記載の血管カテーテル。

【請求項８】　前記カテーテル本体の外表面が親水性高分子物質で覆われている請求項１ないし７のいずれかに記載の血管カテーテル。

【発明の詳細な説明】

【０００１】

【産業上の利用分野】本発明は、血管内手術、制ガン剤等の薬剤の超選択的注入、血管造影等に用いられる血管カテーテルに関する。

【０００２】

【従来の技術】近年、外科的手術を行わず、経皮的に血管内にカテーテルを挿入して血管病変および血管に富んだ病変（動脈瘤、動静脈奇形腫瘍等）の治療を行う血管内手術が盛んになっている。このような手技においては、血管カテーテルを、複雑に屈曲蛇行し、分枝の多い細い血管系の特定の部位に選択的に挿入しなければならない。

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【０００３】例えば、脳血管等に見られる動脈瘤や動静脈奇形腫瘍等に対し施される塞栓術と呼ばれる血管内手術では、細い血管カテーテルの先端を脳内の患部またはその近傍まで選択的に挿入し、血管カテーテルの先端から、シアノアクリレート、エチレンービニルアルコール共重合体のジメチルスルホキシド溶液等の液状の塞栓物質や、ポリビニルアルコールの顆粒等の粒状の塞栓物質、それにコイルを注入する。このように、細い血管への薬剤の投与や造影剤の注入には、それに応じた細径の血管カテーテルが用いられる。

【０００４】従って、このような細径の血管カテーテルには、通常の血管カテーテルに要求される化学的および生物学的安全性に加えて、細く複雑なパターンの血管系に迅速かつ確実な選択性をもって挿入し得るような操作性が要求され、さらには、前述した塞栓物質を注入するために、耐薬品性、特にジメチルスルホキシド等の溶剤に接触したときに変質を生じない耐溶剤性等が要求される。

【０００５】また、血管カテーテルの上記操作性について詳述すると、血管内を挿通させるために術者の押し込む力がカテーテルの基端側から先端側に確実に伝達され得るいわゆる押し込み性と、カテーテルの基端側にて加えられた回転力が先端側に確実に伝達され得るトルク伝達性と、曲がった血管内を予め挿入されたガイドワイヤーに沿って円滑にかつ血管内壁を損傷することなく進み得る追随性（以下、「ガイドワイヤーに対する追随性」または単に「追従性」という）と、目的とする所までカテーテル先端が到達し、ガイドワイヤーを引き抜いた後でも、血管の湾曲、屈曲した部位でカテーテルに折れ曲がりが生じない耐キンク性とが必要とされる。さらには、これらの性質をカテーテルに付与する最大のファクターの１つとして、カテーテルの外表面の潤滑性（摩擦係数の低減による摺動性）が必要とされる。

【０００６】このうち、押し込み性およびガイドワイヤーに対する追随性を付与するための従来技術としては、比較的硬質な内管と、この内管の外面を覆いかつ内管の先端より突出した部分を有する比較的柔質な外管とで構成された、主要長部が２重管構造の血管カテーテルが開発され、使用されている。このような血管カテーテルにおいて、内管および外管の構成材料のとしては、次のような組合わせのものが提案されている。

【０００７】実表昭６０－５０００１３号および対応米国特許４３８５６３５号では、内管にポリアミドを、外管にウレタンを用い、かつ内管の先端部分はその内径が漸増するようにテーパー状に形成された血管カテーテル

が開示されている。しかしながら、この血管カテーテルでは、外管がウレタン製であるため、前記耐溶剤性に乏しく、塞栓術に用いるカテーテルには適さない。

【０００８】また、この考案では、ポリアミドとウレタンの２重管部分からウレタンの１重管部分に移行する境界部において、剛性が急激に変化するため、カテーテル本体に折れ曲がり（キンク）を生じ易いという欠点もある。特に、ウレタンの１重管部分においては、外径および内径が一定であり、剛性が先端に向かって漸減していないため、２重管から１重管に移行する境界部に応力集中が生じ、これがキンクを生じる原因となっており、また、追従性も劣っている。特に、血管内操作を繰り返し行うちに、材質疲労のため、甚しい場合には２重管から１重管に移行する境界部が切断したとの報告が散見される。

【０００９】実公昭６２－１７０８２号では、外管にシリコンゴムを用い、内管にポリエチレン、ポリプロピレン、フッ素樹脂および硬質塩化ビニール樹脂より選ばれた硬質の樹脂を用いた血管カテーテルが開示されている。この血管カテーテルでは、耐溶剤性はあるものの（硬質塩化ビニール樹脂は除く）、２重管の部分（本体部分４）と１重管の部分（先端部３）との境界部において、チューブ内腔に内管の厚さに相当する段差が形成されているため、この部分で折れ曲がりを生じ易く、前記耐キンク性が劣っている。また、近年、実用化されているポリプロピレン製の内管とエチレン－酢酸ビニル共重合体製の外管とを組合わせについても、同様に耐キンク性が劣っている。

【００１０】特開昭５９－１５６３５３号では、ナイロン製の基部側の管状体とポリエーテル－ポリアミド共重合体製の先端部とを融合させて、先端部の柔軟性を適度に徴した血管カテーテルが開示されている。しかしながら、この血管カテーテルは、二重管構造をなすものではなく、異種材料を融合して連結するものであるため、融合部位での切断のおそれや、外表面に段差が形成され、カテーテル挿入時に血管内壁に損傷を与えるおそれがあり、さらには、ポリマーの融合のために特殊な製造装置を用いねばならないという欠点がある。

【００１１】米国特許４６３６３４６号では、３重管構造の主要部と、それより先端方向に延長された２重管構造（主要部の中間層を欠く）の先端部とを有するガイディングカテーテルが開示されている。このカテーテルは、他のカテーテルをその管腔（内腔）に挿入して目的部位へ誘導するためのガイド用のカテーテルであるため、管腔の内径をできる限り大きく採ることが前提とされており、よって、上述した細径の血管カテーテルに適用することは事実上困難である。

【００１２】また、以上に挙げたような血管カテーテルは、いずれも、その外表面の潤滑性に乏しく、血管内での摺動性に劣るため、血管カテーテルを安全にかつ短時間で目的部位に到達させることが困難であった。

【００１３】

【発明が解決しようとする課題】本発明の目的は、押し込み性や追随性、耐キンク性等の操作性に優れ、また血管損傷が少なく、安全性に優れ、特に細径の血管に対する手技にも適した血管カテーテルを提供することにある。

【００１４】

【課題を解決するための手段】このような目的は、下記（１）～（８）の本発明により達成される。

【００１５】（１）　内管と該内管の外面に密着する外管とからなる２重管構造をなし、基端から先端にかけて内部に管腔が形成されたカテーテル本体を有し、前記内管の曲げ弾性率が前記外管の曲げ弾性率より大きい血管カテーテルであって、前記カテーテル本体は、外径が長手方向にほぼ一定で前記内管および前記外管よりなる基部と、該基部の先端からカテーテル本体の先端方向に向かって延長され、少なくともその外径が先端方向に向かって漸減する前記内管および前記外管よりなる中間部と、該中間部の先端からカテーテル本体の先端方向に向って延長され、その外径が先端方向に向かって漸減する前記外管よりなる先端部とで構成され、前記中間部から前記先端部にかけてカテーテル本体の曲げ剛性が漸減し、前記基部と前記中間部との境界部付近および前記中間部と前記先端部との境界部付近において、それぞれカテーテル本体の外表面が連続したなめらかな表面を形成していることを特徴とする血管カテーテル。

【００１６】（２）　前記中間部における前記内管の外径が先端方向に向かって漸減する上記（１）に記載の血管カテーテル。

【００１７】（３）　前記先端部における前記外管の厚さが先端方向に向かって漸減する上記（１）または（２）に記載の血管カテーテル。

【００１８】（４）　前記内管の曲げ弾性率（ＡＳＴＭ　Ｄ－７９０、２３℃）が１５００～１５０００kg/cm^{2}である上記（１）ないし（３）のいずれかに記載の血管カテーテル。

【００１９】（５）　前記内管がポリアミドエラストマーで構成されている上記（１）ないし（４）のいずれかに記載の血管カテーテル。

【００２０】（６）　前記先端部における前記外管の曲げ弾性率（ＡＳＴＭ　Ｄ－７９０、２３℃）が５～１５００kg/cm^{2}である上記（１）ないし（５）のいずれかに記載の血管カテーテル。

【００２１】（７）　前記外管がポリエステルエラストマーで構成されている上記（１）ないし（６）のいずれかに記載の血管カテーテル。

【００２２】（８）　前記カテーテル本体の外表面が親水性高分子物質で覆われている上記（１）ないし（７）のいずれかに記載の血管カテーテル。

【００２３】
【作用】本発明の血管カテーテルは、カテーテル本体の主要部分が、剛性の高い内管と、これに比べ剛性の低い外管とを組み合わせた２重管で構成され、さらに内管の先端より外管が所定長さ突出して、柔軟なカテーテル先端部を形成しているため、径が比較的大きい通常の動脈や静脈はもちろんのこと、例えば脳血管やその他の末梢血管のような微細で複雑な血管内においても、優れた押し込み性、追随性および耐キンク性を発揮し、血管分岐部においては確実な選択性を有し、さらに安全性も高い。

【００２４】さらに詳述すると、本発明の血管カテーテルにおいて、２重管構造の部分は、カテーテル本体の外径が長手方向にほぼ一定である基部と、カテーテル本体の外径が先端方向に向かって漸減する中間部とで構成され、さらに、中間部より先端側に、柔軟な外管のみで構成され、外径が先端方向に向かって漸減する先端部が形成されているため、基部から中間部にかけては、優れた押し込み性やトルク伝達性を発揮し、中間部から先端部にかけては、そのほぼ全域にわたりカテーテル本体の剛性が連続的に減少するので、屈曲した血管に挿入されたガイドワイヤーに対する優れた追随性を発揮し、折れ曲がり（キンク）も防止される。

【００２５】この場合、中間部と先端部においては、外径が先端方向に向かって漸減しているので、カテーテルを血管内に押し込んで行く際の挿通性（走行性）および血管分岐部における選択性が高い。また、基部と中間部との境界部および中間部と先端部との境界部においては、それぞれ、カテーテル本体の外表面が、段差のない連続したなめらかな表面を形成しているので、血管への刺激が少なく、損傷を与えることもない。

【００２６】さらに、中間部における内管の外径が先端方向に向かって漸減するように、すなわち、内管の外面をテーパ状に形成することによって、また材料や寸法の選定により内管および外管の弾性率を適切に調整することによって、前記境界部での剛性の急激な変化や応力集中がなくなり、キンクが生じ難くなる。特に、ポリアミドエラストマーまたはポリエステルエラストマーで構成された内管は、室温付近では比較的剛性が高いため、押し込み性に優れ、また体温付近では柔軟となるので、血管の屈曲によく馴染み、追従性、耐キンク性が一層高まる。

【００２７】また、カテーテル本体の外表面を親水性高分子物質で覆った場合には、血液等に接触して潤滑な表面を形成がされ、血管内での操作性がさらに向上し、血管内壁を損傷することもなく、安全性が一段と高まる。

【００２８】
【発明の構成】以下、本発明を添付図面に示す好適例に基づいて詳細に説明する。図１は、本発明の血管カテーテルの全体構成例を示す平面図、図２は、図１に示す血管カテーテルの先端部付近の構成を拡大して示す縦断面図である。なお、図２では、理解を容易にするために、血管カテーテルの径方向を特に拡大して模式的に示してある。

【００２９】図１に示すように、本発明の血管カテーテル１は、カテーテル本体２と、このカテーテル本体２の基端２１に装着されたハブ１１とで構成されている。カテーテル本体２は、その基端２１から先端２２にかけて内部に管腔３が形成されている。この管腔３は、薬液等の流路となるものであり、血管カテーテル１の血管への挿入時には、管腔３内にガイドワイヤーが挿通される。

ハブ１１は、管腔３内への薬液等の注入口および前記ガイドワイヤーの挿入口として機能し、また、血管カテーテル１を操作する際の把持部としても機能する。

【００３０】図２に示すように、カテーテル本体２は、その主要部分が、内管４と該内管４の外面に密着、接合された外管５とからなる２重管構造をなしている。内管４は、比較的剛性の大きい材料で構成されており、外管５は、比較的柔軟な材料で構成されている。また、カテーテル本体２は、基端２１側から順に、基部６、中間部７および先端部８で構成されている。これらのうち、基部６および中間部７が前記２重管構造をなしており、先端部８は、外管５のみで構成されている。

【００３１】基部６においては、カテーテル本体２の外径がカテーテル長手方向にほぼ一定である。また、カテーテル本体２の内径（管腔３の直径）も同様にほぼ一定であるのが好ましい。

【００３２】中間部７においては、カテーテル本体２の外径が先端２２の方向（以下、先端方向という）に向かって漸減している。また、中間部７において、内管４の外径が先端方向に向かって漸減するのが好ましく、さらには、カテーテル本体２の内径は長手方向にほぼ一定であるのが好ましい。これにより、内管４の厚さは、先端方向に向かって徐々に薄くなり、その剛性も連続的に減少する。

【００３３】先端部８は、内管４が欠如し、外管５のみで構成されている。この先端部８においては、カテーテル本体２の外径が先端方向に向かって漸減している。また、先端部８において、外管５の厚さは、図示のように、カテーテル長手方向にほぼ一定であってもよいが、管腔３の直径を一定またはその減少率を低くして、ガイドワイヤーの挿通性を向上するために、外管５全域または一部の厚さが先端方向に向かって漸減するのが好ましい。なお、このような構成とすることは、先端部８の剛性を先端方向に連続的に減少させるのにも有利であり、追随性、安全性の向上にとっても好ましい。

【００３４】なお、中間部７におけるカテーテル本体２の外表面のテーパ角度と、先端部８におけるカテーテル本体２の外表面のテーパ角度とは、図２に示すように同一であっても、また異なっていてもよい。基部６と中間

部７との境界部９においては、カテーテル本体２の外表面が連続したなめらかな表面（例えば、カテーテル長手方向に湾曲する面）を形成しており、実質的に段差が形成されていない。これにより、カテーテル挿入に際して血管への刺激が少なく、血管内壁に損傷を与えることも防止され、しかもシースのようなカテーテル挿入器具の挿入口を通過する際に引っかかり、境界部９が摩耗することも防止される。

【００３５】また、中間部７と先端部８との境界部１０においても、同様に、カテーテル本体２の外表面が連続面を形成しており、段差が形成されていないので、前記と同様の効果が得られる。なお、中間部７におけるカテーテル本体２の外表面のテーパ角度と、先端部８におけるカテーテル本体２の外表面のテーパ角度とが異なっている場合には、境界部１０におけるカテーテル本体２の外表面が、前記境界部９と同様に、連続したなめらかな表面を形成しているのが好ましい。

【００３６】内管４の構成材料としては、例えば、ポリプロピレン、ポリエチレン等のポリオレフィン、ポリアミド、ポリエチレンテレフタレート、ポリブチレンテレフタレート等のポリエステル、ポリウレタン、ポリ塩化ビニル、ポリスチレン系樹脂、エチレンーテトラフルオロエチレン共重合体等のフッ素系樹脂、ポリイミド等各種可撓性を有する樹脂や、ポリアミドエラストマー、ポリエステルエラストマー、ポリウレタンエラストマー等の各種エラストマーが使用可能であるが、そのなかでも特に、ポリアミドエラストマーまたはポリエステルエラストマーが好ましく、ポリアミドエラストマーがより好ましい。このような材料を用いることにより、内管４として最適な曲げ弾性率が得られ、また、耐溶剤性が高く、耐キンク性等に優れている。また、ポリアミドエラストマーおよびポリエステルエラストマーは、室温付近では比較的剛性が高いため、押し込み性やトルク伝達性に優れ、また体温付近では柔軟となるので、体内に挿入後はより血管の屈曲によく馴染み、追従性、耐キンク性が一層高まる。

【００３７】ここで、ポリアミドエラストマーとは、例えば、ナイロン６、ナイロン６４、ナイロン６６、ナイロン６１０、ナイロン６１２、ナイロン４６、ナイロン９、ナナイロン１１、ナイロン１２、Ｎ－アルコキシメチル変性ナイロン、ヘキサメチレンジアミンーイソフタル酸縮重合体、メタキシロイルジアミンーアジピン酸縮重合体のような各種脂肪族または芳香族ポリアミドをハードセグメントとし、ポリエステル、ポリエーテル等のポリマーをソフトセグメントとするブロック共重合体が代表的であり、その他、前記ポリアミドと柔軟性に富む樹脂とのポリマーアロイ（ポリマーブレンド、グラフト重合、ランダム重合等）や、前記ポリアミドを可塑剤等で軟質化したもの、さらには、これらの混合物をも含む概念である。

【００３８】なお、前記可塑剤は、溶剤や血液等で抽出され難いものを用いるのが好ましい。また、ポリエステルエラストマーとは、ポリエチレンテレフタレート、ポリブチレンテレフタレート等の飽和ポリエステルと、ポリエーテルまたはポリエステルとのブロック共重合体が代表的であり、その他、これらのポリマーアロイや前記飽和ポリエステルを可塑剤等で軟質化したもの、さらには、これらの混合物をも含む概念である。

【００３９】なお、前記ポリアミドエラストマーまたはポリエステルエラストマーには、必要に応じ、アロイ化剤、相溶化剤、硬化剤、軟化剤、造影剤、安定剤、着色剤等の各種添加物を配合してもよい。この場合、添加成分が溶剤、薬液、血液等で抽出され難いものを用いるのが好ましい。また、内管４の材質は、通常、その長手方向に沿って同一とされるが、必要に応じ、部位によってその組成が異なっていてもよい。

【００４０】外管５の構成材料としては、例えば、ポリプロピレン、ポリエチレン（特に、低密度ポリエチレン）、エチレンー酢酸ビニル共重合体等のポリオレフィン、前記ポリアミドエラストマー、前記ポリエステルエラストマー、ポリウレタンエラストマー、軟質ポリ塩化ビニル、ポリスチレンエラストマー、フッ素系エラストマー、シリコーンゴム、ラテックスゴム等の各種柔軟性に富む樹脂やエラストマーが使用可能であるが、そのなかでも特に、前記と同様の理由から、ポリアミドエラストマーまたはポリエステルエラストマーが好ましく、ポリエステルエラストマーがより好ましい。

【００４１】また、外管５の材質は、通常、その長手方向に沿って同一とされるが、必要に応じ、部位によってその組成が異なっていてもよい。一般に、物体の曲げ剛性は、曲げ弾性率Ｅと断面２次モーメントＩの積で表される。円筒状の管状体であるカテーテル本体の断面２次モーメントＩは外径Ｄ$_o$および内径Ｄ$_i$から決定され、下記数１の式で示される。

【００４２】

【数１】

$$I = \frac{\pi (D_o^4 - D_i^4)}{64}$$

【００４３】すなわち、外径Ｄ$_o$が大きくなればなるほど、また、外径Ｄ$_o$が一定の場合には、外径Ｄ$_o$と内径Ｄ$_i$との差が大きいほど剛性も高くなる。血管カテーテルの場合、カテーテル本体２の外径および内径は、多くの場合、適用する血管系や手技により規制され、経験的に外径と内径の差が小さくなる傾向を示すので、カテーテル本体の剛性が低くなり、折れ曲がり防止にとっては不利になる。従って、必要かつ十分な剛性を得るには、材料の曲げ弾性率を基準として材料選択を行うのが好ましい。

【００４４】本発明において、基部６および中間部７の

剛性は、主に押し込み性やトルク伝達性を左右するものであり、その大半が内管４の剛性に委ねられている。また、先端部８の剛性は、主に追従性や突当て抵抗（特に、屈曲した血管への圧迫）を左右するものであり、外管５の剛性に等しい。そして、内管４の剛性と外管５の剛性とのバランスが、耐キンク性を大きく左右する。このようなことから、内管４および外管５の曲げ剛性を適正な値とすることが必要であり、具体的には、以下のような範囲とするのが好ましい。

【００４５】内管４の曲げ弾性率（ＡＳＴＭ　Ｄ－７９０、２３℃）は、１５００～１５０００kg/cm^{2}であるのが好ましく、２０００～８０００kg/cm^{2}であるのがより好ましい。これが１５００kg/cm^{2}未満であると、押し込み性やトルク伝達性が劣り、１５０００kg/cm^{2}を超えると、ガイドワイヤーに対する追随性が悪くなり、柔軟な血管内壁への負荷が増大し、しかも、先端部８との剛性の差が大きくなり、境界部１０でキンクが生じ易くなる。

【００４６】外管５、特に先端部８における外管５の曲げ弾性率（ＡＳＴＭ　Ｄ－７９０、２３℃）は、５～１５００kg/cm^{2}であるのが好ましく、３００～８００kg/cm^{2}であるのがより好ましい。これが５kg/cm^{2}未満であると、基部６からの押し込む力やトルクが先端２２付近まで伝達され難くなり、また、中間部７と先端部８との剛性の差が大きくなり、境界部１０でキンクが生じ易くなり、１５００kg/cm^{2}を超えると、ガイドワイヤーに対する追随性が悪くなり、血管内壁に与える刺激が大きくなる。

＊【００４７】また、内管４と外管５との曲げ弾性率（ＡＳＴＭ　Ｄ－７９０、２３℃）の差は、１００～１４０００kg/cm^{2}程度であるのが好ましく、１００～６０００kg/cm^{2}程度であるのがより好ましい。なお、本明細書において、内管や外管の曲げ弾性率とは、内管や外管を構成する材料の曲げ弾性率のことを言う。本発明において、内管４と外管５との接合は、内管４の外周面と外管５の内周面とが密着するようになされ、その方法としては、例えば、内管４と外管５とを接着剤または溶剤により接着する方法、内管４と外管５とを融着（例えば、熱融着、高周波融着）する方法、外管５を溶剤で膨張させて内管４を挿入する方法、または内管４と外管５とを２色押出成形により一体的に形成する方法が挙げられる。

【００４８】本発明において、カテーテル本体２の寸法は特に限定されないが、例えば、脳血管に挿入して使用される血管カテーテルの場合、カテーテル本体２の全長は、５０～２００cm程度、特に７０～１５０cm程度が好ましく、中間部７の長さは、５～３０cm程度、特に１０～２０cm程度が好ましく、先端部８の長さは、７～３５cm程度、特に１０～２０cm程度が好ましい。このような範囲において、カテーテル本体２の各部の曲げ剛性のバランスが良好となり、上述した効果を有効に発揮する。また、同様の観点から、基部６、中間部７および先端部８におけるその他の寸法は、下記表１に示す範囲とするのが好ましい。

【００４９】

【表１】

表　１　　（単位：mm）

	基部６	中間部７	先端部８
外　径	0.6 ～2.0 (0.7 ～1.2)	0.5 ～1.6 ＊ (0.7 ～1.0)	0.3 ～1.0 ＊ (0.6 ～0.9)
内　径	0.2 ～1.6 (0.3 ～0.9)	0.2 ～1.3 (0.3 ～0.7)	0.2 ～0.7 ＊ (0.3 ～0.6)
外管厚さ	0.05～0.3 (0.05～0.2)	0.03～0.3 (0.05～0.15)	0.05～ 0.3 (0.05～0.15)
内管厚さ	0.05～0.5 (0.08～0.3)	0.025～0.25＊ (0.01～0.2)	――

かっこ内は、より好ましい範囲を示す
＊印は、平均値を示す

【００５０】本発明では、カテーテル本体２の外表面が、親水性（または水溶性）高分子物質で覆われている（図示せず）ことが好ましい。これにより、カテーテル本体２の外表面が血液または生理食塩水等に接触したときに、摩擦係数が減少して潤滑性が付与され、カテーテル本体２の摺動性が一段と向上し、その結果、押し込み性、追随性、耐キンク性および安全性が一段と高まる。親水性高分子物質としては、以下のような天然または合

成の高分子物質、あるいはその誘導体が挙げられる。

【００５１】＜天然高分子物質＞

１）デンプン系

例：カルボキシルメチルデンプン、ジアルデヒドデンプン

２）セルロース系

例：ＣＭＣ、ＭＣ、ＨＥＣ、ＨＰＣ

３）タンニン、ニグニン系

例：タンニン、ニグニン

４）多糖類系

例：アルギン酸、アラビアゴム、グアーガム、トラガントガム、タマリント種

５）タンパク質

例：ゼラチン、カゼイン、にかわ、コラーゲン

【００５２】＜合成水溶性高分子＞

１）ＰＶＡ系

例：ポリビニルアルコール

２）ポリエチレンオキサイド系

例：ポリエチレンオキサイド、ポリエチレングリコール

３）アクリル酸系

例：ポリアクリル酸ソーダ

４）無水マレイン酸系

例：メチルビニルエーテル無水マレイン酸共重合体

５）フタル酸系

例：ポリヒドロキシエチルフタル酸エステル

６）水溶性ポリエステル

例：ポリジメチルロールプロピオン酸エステル

７）ケトンアルデヒド樹脂

例：メチルイソプロピルケトンホルムアルデヒド樹脂

８）アクリルアミド系

例：ポリアクリルアミド

９）ポリビニルピロリドン系

例：ＰＶＰ

10）ポリアミン系

例：ポリエチレンイミン

11）ポリ電解質

例：ポリスチレンスルホネート

12）その他

例：水溶性ナイロン

【００５３】これらのうちでも、特に、セルロース系高分子物質（例えば、ヒドロキシプロピルセルロース）、ポリエチレンオキサイド系高分子物質（ポリエチレングリコール）、無水マレイン酸系高分子物質（例えば、メチルビニルエーテル無水マレイン酸共重合体のような無水マレイン酸共重合体）、アクリルアミド系高分子物質（例えば、ポリアクリルアミド）、水溶性ナイロン（例えば、東レ社製のＡＱ－ナイロン　Ｐ－７０）は、低い摩擦係数が安定的に得られるので好ましい。また、上記高分子物質の誘導体としては、水溶性のものに限定されず、上記水溶性高分子物質を基本構成としていれば、特

に制限はなく、不溶化されたものであっても、分子鎖に自由度があり、かつ含水するものであればよい。

【００５４】例えば、上記高分子物質の縮合、付加、置換、酸化、還元反応等で得られるエステル化物、塩、アミド化物、無水物、ハロゲン化物、エーテル化物、加水分解物、アセタール化物、ホルマール化物、アルキロール化物、４級化物、ジアゾ化物、ヒドラジド化物、スルホン化物、ニトロ化物、イオンコンプレックス；ジアゾニウム基、アジド基、イソシアネート基、酸クロリド基、酸無水物基、イミノ炭酸エステル基、アミノ基、カルボキシル基、エポキシ基、水酸基、アルラヒド基等、反応性官能基を２個以上有する物質との架橋物；ビニル化合物、アクリル酸、メタクリル酸、ジエン系化合物、無水マレイン酸等との共重合物等が挙げられる。

【００５５】このような、親水性高分子物質の被覆層をカテーテル本体２の外表面に固定するには、外管５中もしくは外管５の表面に存在または導入された反応性官能基と共有結合させることにより行うのが好ましい。これにより、持続的な潤滑性表面を得ることができる。外管５中または表面に存在しまたは導入される反応性官能基は、前記高分子物質と反応し、結合ないし架橋して固定するものであればいかなるものでもよく、ジアゾニウム基、アジド基、イソシアネート基、酸クロリド基、酸無水物基、イミノ炭酸エステル基、アミノ基、カルボキシル基、エポキシ基、水酸基、アルデヒド基等が挙げられ、特にイソシアネート基、アミノ基、アルデヒド基、エポキシ基が好適である。

【００５６】本発明における親水性高分子物質の平均分子量は、特に限定されないが、３～５００万程度のものが好ましい。これにより、潤滑性が高く、適度な厚さでかつ含水時における膨潤度が適度である潤滑層が得られる。このような親水性高分子物質による潤滑層の厚さは特に限定されないが、０．１～１００μｍ程度、特に１～３０μｍ程度とするのが好ましい。なお、本発明における親水性高分子物質の組成や被覆方法については、例えば、特開昭５３－１０６７７８号、米国特許第４１００３０９号、特開昭６０－２５９２６９号、特公平１－３３１８１号に記載されているようなものを適用することができる。

【００５７】

【実施例】以下、本発明の具体的実施例について説明する。

（実施例）ポリプロピレンオキサイドとナイロン６１０との共重合体であるポリアミドエラストマーにより内管４の成形体を製造し、一方、ポリテトラメチレンオキサイドとポリブチレンテレフタレートとの共重合体であるポリエステルエラストマーにより外管５の成形体を製造し、この外管５内に前記内管４を挿入し、これらを融着して、図２に示す構造のカテーテル本体２を作製した。

【００５８】なお、前記内管４の曲げ弾性率（ＡＳＴＭ

D－790、23℃）は5000kg/cm²であり、前記外管5の曲げ弾性率（ASTM D－790、23℃）は720kg/cm²であった。次に、特公平1－33181号に記載された方法により、前記カテーテル本体2の外表面のほぼ全域に、親水性高分子物質であるメチルビニルエーテル無水マレイン酸共重合体の被覆層を形成し、その後、カテーテル本体の基端21にハブ11を装着して本発明の血管カテーテルを得た。

【0059】なお、カテーテル本体2の各部の寸法は、以下の通りである。

カテーテル本体全長：150cm
基部長さ　：110cm
基部外径　：1．1mm
基部内径　：0．65mm
中間部長さ：20cm
中間部外径：1．1mmから0．90mmに漸減
中間部内径：0．65mm
先端部長さ：20cm
先端部外径：0．90mmから0．74mmに漸減
先端部内径：0．65mmから0．54mmに漸減

【0060】（比較例）ポリプロピレンにより内管14の成形体を製造し、一方、エチレン－酢酸ビニル共重合体により外管15の成形体を製造し、この外管15内に前記内管14を挿入し、これらを融着して、図3に示すような、基部16が2重管、先端部18が外管5のみで構成されたカテーテル本体12を作製した。なお、このカテーテル本体12は、中間部に相当する部分を有していない。次に、このカテーテル本体12の基端に前記実施例と同様のハブ11を装着して比較例の血管カテーテル1'を得た。

【0061】なお、カテーテル本体12の各部の寸法は、以下の通りである。

カテーテル本体全長：146cm
基部長さ　：128cm
基部外径　：0．94mm
基部内径　：0．61mm
先端部長さ：18cm
先端部外径：0．74mm
先端部外径：0．54mm

【0062】［実験1］上記実施例および比較例の血管カテーテルに対し、耐キンク性を調べるために、以下のような折れ曲がり試験を行った。円筒状の固定器具内に、カテーテル本体をその中間部の約半分長さの位置まで挿入して固定し、一方、カテーテル本体の管腔内に、ワイヤーをカテーテル本体の先端側から先端部の約半分の長さの位置まで挿入し、37℃の水中にて、ワイヤーをその先端（管腔内側）を中心にその基端が弧を描くように徐々に移動し、中間部と先端部との境界に折れ目が生じたときの基部の軸線と先端部の軸線とのなす角度θを測定（測定回数5回）した。

【0063】その結果、上記本発明の実施例の血管カテーテルでは、θ＝71．0°であるのに対し、上記比較例の血管カテーテルでは、θ＝64．1°であり、本発明の血管カテーテルは、耐キンク性が優れていることが確認された。

【0064】［実験2］上記実施例および比較例の血管カテーテルを用いて以下のような動物実験を行い、血管カテーテルの操作性を調べた。カテーテルの管腔内にガイドワイヤーを挿通した状態で、家兎の頸動脈より、カテーテル本体を挿入し、その先端を、腹部大動脈を経て腸間膜動脈の末梢部まで導入した。血管の分岐部においては、ガイドワイヤーの進退、カテーテルの進退および回転を適宜組み合わせて血管を選択した。

【0065】上記本発明の実施例の血管カテーテルでは、血管との摩擦が小さく、押し込み性および回転の際のトルク伝達性が極めて良好で、分岐部における血管の選択性やガイドワイヤーに対する追従性も良好であり、特に、細径の末梢血管においてもこのような効果が発揮されていた。このようなことから、カテーテル挿入の操作が容易であり、カテーテルの先端が目的部位へ到達するまでの時間も短時間（約5分）であった。

【0066】これに対し、上記比較例の血管カテーテルでは、押し込み性およびトルク伝達性に問題があり、分岐部における血管の選択に手間がかかり、ガイドワイヤーに対する追従性も劣り、特に、細径の末梢血管においては、このような欠点が顕著であった。従って、カテーテル挿入の操作に困難を伴い、カテーテルの先端が目的部位へ到達するまでの時間も、前記本発明に比べ長時間（約15分）であった。

【0067】

【発明の効果】以上述べたように、本発明の血管カテーテルによれば、カテーテル本体の主要部分が、剛性の高い内管と、これに比べ剛性の低い外管とを組み合わせた2重管で構成されており、この2重管の部分は、カテーテル本体の外径が長手方向にほぼ一定である基部と、カテーテル本体の外径が先端方向に向かって漸減する中間部とで構成され、さらに、中間部より先端側の先端部は、外径が漸減する柔軟な外管で構成されているため、押し込み性、トルク伝達性、屈曲した血管に挿入されたガイドワイヤーに対する追随性、耐キンク性、血管分岐部における選択性が向上し、また、血管への刺激が少なく、血管内壁の損傷が防止され、安全性も高い。

【0068】また、カテーテル本体の外表面を親水性高分子物質で覆った場合には、血液等に接触して潤滑な表面を形成がされ、摩擦抵抗が減少するので、上記効果が一段と高まる。このような本発明の効果は、径が比較的大きい通常の動脈や静脈はもちろんのこと、例えば脳血管やその他の末梢血管のような、径が小さくかつ分岐が多く、屈曲蛇行した血管内に選択的に挿入する際にも有効に発揮される。

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【図面の簡単な説明】

【図１】本発明の血管カテーテルの構成例を示す平面図である。

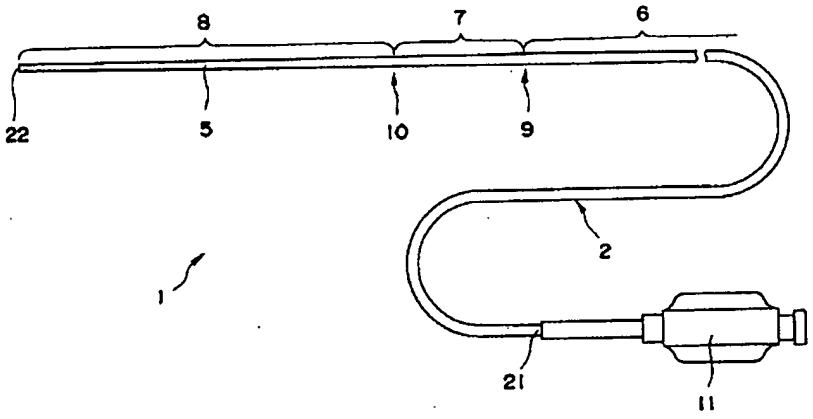
【図２】図１に示す血管カテーテルの先端部付近の構成を拡大して模式的に示す縦断面図である。

【図３】比較例の血管カテーテルの先端部付近の構成を拡大して模式的に示す縦断面図である。

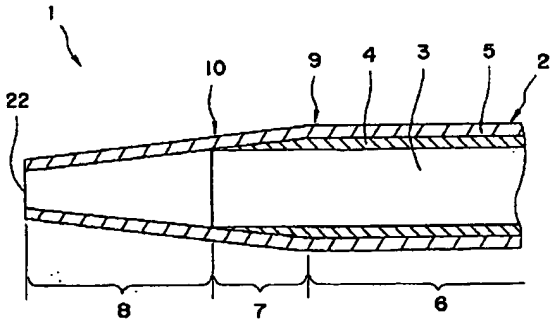
【符号の説明】

1	血管カテーテル（本発明）		＊３	管腔
1'	血管カテーテル（比較例）		４	内管
２	カテーテル本体		５	外管
２１	基端		６	基部
２２	先端		７	中間部
			８	先端部
			９、１０	境界部
			１１	ハブ
			１２	カテーテル本体
		10	１４	内管
			１５	外管
			１６	基部
		＊	１８	先端部

【図１】



【図２】



【図３】